



Dietary Supplements: A Review of United States Regulation with Emphasis on the Dietary Supplement Health and Education Act of 1994 and Subsequent Activity

Citation

Dietary Supplements: A Review of United States Regulation with Emphasis on the Dietary Supplement Health and Education Act of 1994 and Subsequent Activity (2004 Third Year Paper)

Permanent link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:8852160>

Terms of Use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA>

Share Your Story

The Harvard community has made this article openly available.
Please share how this access benefits you. [Submit a story](#).

[Accessibility](#)

DIETARY SUPPLEMENTS: A REVIEW OF UNITED STATES REGULATION WITH EMPHASIS ON THE DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994 AND SUBSEQUENT ACTIVITY

Brian Scarbrough

Class of 2004

April 2004

This paper is submitted in satisfaction of both the course requirement and the third year written work requirement

ABSTRACT

This paper undertakes a review of notable dietary supplement regulation in the United States. First, this paper discusses dietary supplements generally and their uses and economic characteristics. Second, this paper discusses a brief general history of dietary supplement regulation in the United States including the Dietary Supplement Health and Education Act of 1994 (“DSHEA”). Emphasis is placed on the DSHEA and notable post-DSHEA governance in the form of Food and Drug Administration regulations, congressional activity, and other administrative and industry action. Finally, this paper proposes how the United States, both through government regulation and industry self-regulation, should proceed to handle dietary supplements in 2004 and beyond.

I. INTRODUCTION

Food and drugs – at first glance they seem worlds apart but upon closer inspection their boundaries start to merge. For decades, Congress and the Food and Drug Administration (“FDA”) struggled to define such boundaries until they finally created an intermediate product group called dietary supplements. The Dietary Supplement Health and Education Act of 1994 (“DSHEA”) established the statutory category of dietary supplements and subjected them to various food standards as well as a host of new standards.¹ The DSHEA attempted to strike a balance between foods that are functional in that they have some health benefits and drugs that have clearly defined and approved health benefits. Since passage of the DSHEA, Congress, the FDA, and the dietary supplement industry have strove, with varying degrees of success, to implement the DSHEA and give definition to the ever expanding and extremely popular dietary supplement market.

II. GENERAL BACKGROUND REGARDING DIETARY SUPPLEMENTS

A. Types of Dietary Supplements

Dietary supplements are defined in the DSHEA (now codified in scattered sections of Title 21 of the United States Code) as a product other than tobacco which includes one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, any other substance used to supplement the diet by increasing total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of the above.² Whatever the form, dietary supplements are considered a special category of food and

¹Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified as amended in scattered sections of 21 U. S. C.).

²Pub. L. No. 103-417, § 3 (codified at 21 U. S. C. § 321(ff)(1)(A-F)). A dietary supplement also must be intended for ingestion in tablet, capsule, powder, soft gel, or liquid form. *Id.* (codified at 21 U. S. C. §§ 321(ff)(2)(A)(i), 350(c)(1)(B)(i)). Further, if the dietary supplement is not intended for ingestion in such form, it must not be represented as conventional food and not represented as meal replacement. *Id.* (codified at 21 U. S. C. §§321(ff)(2)(A)(ii), 350(c)(1)(B)(ii)). Further, the dietary supplement, no matter the form, must not be represented for use as conventional food or meal replacement. *Id.* (codified at 21 U. S. C. § 321(ff)(2)(B)). Further, the dietary supplement must be labeled as a dietary supplement. *Id.* (codified at 21 U. S. C.

are not considered drugs.³

The main categories of dietary supplements in the United States are as follows: vitamins,⁴ minerals,⁵ herbals and botanicals (including extracts),⁶ animal extracts,⁷ amino acids,⁸ proteins,⁹ concentrates, metabolites, and constituents,¹⁰ teas,¹¹ and miscellaneous products.¹² Currently in the United States, dietary supplements play a key role alongside nutraceuticals¹³ and functional foods¹⁴ in the ever expanding consumer

§ 321(ff)(2)(C). Finally, the dietary supplement definition includes and excludes certain drugs. *Id.* (codified at 21 U. S. C. § 321(ff)(3)).

³*Id.* (codified at 21 U. S. C. § 321(ff)); *but see* 21 U. S. C. § 321(ff)(3) (in certain limited cases a dietary supplement can be a drug). I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 1 (1996);

⁴Vitamins are defined as “[p]roducts that are organic (carbon-containing) nutrients that are essential in small quantities for normal metabolism, growth, and well-being. They must be obtained through the diet because they either are not synthesized in the body or are not synthesized in adequate amounts.” CENTER FOR ECONOMICS RESEARCH, RESEARCH TRIANGLE INSTITUTE, ECONOMIC CHARACTERIZATION OF THE DIETARY SUPPLEMENT INDUSTRY 1-1 (Final Report 1999) [Hereinafter ECONOMIC CHARACTERIZATION]. There are thirteen vitamins necessary for human consumption: A, D, E, K (all fat-soluble) and B₁, B₂, B₃, B₆, B₁₂, C, biotin, folic acid, and pantothenic acid (all water-soluble). *Id.* at 2-1.

⁵Minerals are defined as “[p]roducts that are chemical elements in their inorganic form. ‘Minerals’ are those that are required in amounts greater than 100mg/day, and ‘trace minerals’ are those required in lesser amounts.” *Id.* at 1-1. There are seventeen minerals commonly used in dietary supplements. *Id.* at 2-4. *See id.* at 2-5 for a table of these seventeen commonly used minerals, their occurrence in foods, and the forms they take in supplements.

⁶Herbal refers to leaves and stems of a plant while botanical refers to roots, seeds, fruits, and any other part of a plant in addition to leaves and stems of a plant. *Id.* at 1-1, 4-14. Herbal or botanical extracts are made from any part of a plant. *Id.*

⁷Animal extracts are “[p]roducts that are extracts of made from animal parts.” *Id.* at 1-1. These extracts are from particular animal tissues or glands. *Id.* at 4-23.

⁸Amino acids are “[p]roducts that contain an amino group and an acidic function.” *Id.* at 1-1. They are the main constituent of proteins and are classified as either essential (not synthesized in the human body) or non-essential (synthesized in the human body). *Id.* at 4-14.

⁹Proteins are “[p]roducts with the complete set of amino acids to make up proteins.” *Id.* at 1-1. They are “antibodies as part of the immune system” and are key in regulating many body functions. *Id.* at 4-14.

¹⁰Concentrates, metabolites, and constituents refer to any products falling within the other definitions of dietary supplement and broken into individual parts or components. *See id.* at 1-1.

¹¹Teas refer to “[p]roducts infused in water that contain herbals, botanicals, or other... [dietary supplement] products. Basic tea products have a standard of identity as a food product; however, many products are a combination of tea and dietary supplements.” *Id.* at 1-1.

¹²Miscellaneous products refers to “[a]ll other products meeting the criteria of dietary supplements that cannot be classified into the categories above. They include, for example, bee pollen,

propolis, and royal jelly; coenzyme Q; spirulina and other algae; and nucleic acids.” *Id.* at 1-1.

¹³One definition of nutraceutical “is a product isolated or purified from foods that is generally sold in medicinal form not usually associated with food. A nutraceutical is demonstrated to have physiological benefit or provide protection against chronic disease.” Steven Dentali, *Regulation of Functional Foods and Dietary Supplements*, FOOD TECHNOLOGY, June 2002, at 90. Another definition for nutraceutical is “a food, dietary supplement, or medical food that has a medical or health benefit, including the prevention and treatment of disease.” *Functional Foods Market Growing*, FOOD TECHNOLOGY, Dec. 2003, at 90.

¹⁴One definition of functional food is a product “similar in appearance to, or may be, a conventional food, [which] is consumed as part of a usual diet and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions.” Dentali, *supra* note 13, at 90. Neither this definition nor the definition of nutraceutical has any current

health market.

Dietary supplements commonly take several distinct forms. The DSHEA delineates what forms a dietary supplement may take and thus plays a role in funneling dietary supplements into these certain forms.¹⁵ The predominate forms of dietary supplements for purchase by consumers are capsules (both hard-shell and soft-gel), tablets, liquids (including solutions, elixirs, and syrups), powders and granules, and lozenges (substances produced to dissolve over time in the mouth).¹⁶ Additionally, “dietary supplements are allowed to be sold in conventional food form so long as the product ‘is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.’”¹⁷

An illustrative part of the vast dietary supplement market is the sports supplement market.¹⁸ Currently, sports supplements enjoy enormous popularity within the broader sports nutrition market. The sports nutrition market includes products that “focus on boosting energy [and recovery], increasing muscle mass, or improving muscle restoration.”¹⁹ Both dietary supplements and functional foods compose the sports nutrition market and are mostly sold in the forms of “[n]utrition bars, energy drinks, sports beverages, and protein mixes.”²⁰ Current examples of nutrition bars are PowerBar and Clif Bar and current examples of energy drinks are Invigor8, E20, and SoBe No Fear.²¹ B vitamins often appear in energy drinks and

legal status in the United States. Dentali, *supra* note 13, at 90. Often the term nutraceutical and the term functional food are used interchangeably. *Functional Foods Market Growing*, *supra* note 13.

¹⁵See *supra* note 2.

¹⁶See ECONOMIC CHARACTERIZATION, *supra* note 4, at 2-14 to 2-17. Liquids should be intended for consumption in small amounts. Dentali, *supra* note 13, at 90.

¹⁷Dentali, *supra* note 13, at 90 (quoting 21 U. S. C. § 350(c)(1)(B)(ii)).

¹⁸Sports supplements are also referred to as performance-enhancing products or ergogenic aids. Linda Milo Ohr, *More for the Sport*, FOOD TECHNOLOGY, Feb. 2003, at 63.

¹⁹*Id.*

²⁰*Id.*

²¹Linda Milo Ohr, *In Search of More Energy*, FOOD TECHNOLOGY, March 2004, at 55, 56 [hereinafter *Energy*]. While these products are marketed as conventional food and not dietary supplements, they contain ingredients such as taurine, ginseng, or guarana, which otherwise lie within the definition of dietary supplement. Were such beverages marketed as dietary supplements they would fall within the DSHEA definition. For the interaction between conventional foods (particularly functional foods and nutraceuticals) and dietary supplements see Dentali, *supra* note 13, at 89-94.

sports beverages because of their role in energy production and tissue repair and maintenance.²² Taurine, an amino acid, is a popular sports supplement for its fat absorbing antioxidant and membrane-stabilizing properties.²³ Vitamin E, also a popular sports supplement, is used for its role in reducing damaging free radical activity in the body after exercise.²⁴ Protein is used as a sports supplement to maintain muscle tissue and is found in both soy varieties (in nutrition bars) and whey varieties.²⁵ Other sports supplements include creatine, which is thought to increase muscle mass and augment intense exercise capability,²⁶ and carnitine, a metabolite amino acid derivative used to benefit sport performance and recovery.²⁷ Some final examples of sports supplements used for their energy boosting properties include: guarna (botanical), ginseng (an herb), and D-ribose (an amino acid).²⁸

B. The Dietary Supplement Industry: Economics and Sales

There are five main dietary supplement industry groups in the United States: the Council for Responsible Nutrition, the American Herbal Productions Association, the Nonprescription Drug Manufacturers Association (focusing on vitamin and mineral supplements), the Utah Natural Products Alliance, and the National Nutritional Foods Association (the largest such industry group).²⁹

In general, the dietary supplement industry is characterized by high material costs (source costs) with much

²²Ohr, *supra* note 18, at 63, 65.

²³See *Energy*, *supra* note 21, at 56, 66.

²⁴Ohr, *supra* note 18, at 65.

²⁵*Id.*

²⁶*Id.* at 66.

²⁷See *id.* at 68.

²⁸*Energy*, *supra* note 21, at 56, 66.

²⁹ECONOMIC CHARACTERIZATION, *supra* note 4, at 3-1.

lower labor costs.³⁰ Thus the raw materials that compose dietary supplements are the most important part of the dietary supplement industry. To handle these important raw materials, there are estimated to be over 1,100 dietary supplement raw materials and manufacturing firms.³¹ The vast majority (over 78%) of these firms either solely manufactures dietary supplements or manufactures dietary supplements in combination with other functions such as importing or exporting.³² Over 54% of dietary supplement firms produce or handle vitamins and minerals.³³ Herbals and botanicals are produced or handled in 43% of dietary supplement firms.³⁴

The dietary supplement market is composed of many heterogeneous products. A brief look at the definition of dietary supplement under the DSHEA confirms this.³⁵ This causes the cross-price elasticity of demand for dietary supplement to be small which in turn means there is little economic substitution effect among dietary supplements.³⁶ The substitution effects between dietary supplements and non-dietary supplement products are also limited.³⁷

Dietary supplement sales have been growing rapidly. In 2002 (the most recent year for which figures are available), retail sales of dietary supplements were \$18 billion, up 4% from 2001³⁸ and up 310% from a 1997

³⁰See *id.* at 2-18 to 2-19.

³¹*Id.* at 3-1. Another study in 2000 estimated there to be 1,973 such establishments. CENTER FOR ECONOMICS RESEARCH, RESEARCH TRIANGLE INSTITUTE, SURVEY OF MANUFACTURING PRACTICES IN THE DIETARY SUPPLEMENT INDUSTRY 2-1 (Final Report 2000).

³²See ECONOMIC CHARACTERIZATION, *supra* note 4, at 3-1. Aside from manufacturing or importing and exporting, dietary supplement firms may also perform input supply, repacking, relabeling, encapsulating, and distribution. *Id.*

³³*Id.* at 3-2.

³⁴*Id.* Herbal and botanical extracts followed at 14%, teas at 10%, amino acids at 4%, and animal extracts at 2% (percentages add to more than 100 due to overlap in production or handling by firms). *Id.*

³⁵See *supra* notes 4-12.

³⁶ECONOMIC CHARACTERIZATION, *supra* note 4, at 4-29.

³⁷See *id.* at 4-30 to 4-31. Dietary supplements are imperfect substitutes for conventional or fortified foods because consumers cannot receive all daily needed nutrients solely from dietary supplements. *Id.* at 4-30. Further, dietary supplements are imperfect substitutes for conventional medical care because only a tiny percentage of consumers rely completely on dietary supplements for medical care. *Id.* at 4-31.

³⁸National Nutritional Foods Association, *Industry Facts* (2002) (*citing* NUTRITIONAL BUSINESS JOURNAL), *available at* <http://www.nnfa.org/news/industry/index.htm>.

estimate of \$5.8 billion.³⁹ This comprised 32% of the nutrition industry.⁴⁰ When dietary supplements are combined with functional foods, the total sales for 2002 were \$29.8 billion comprising 67% of the nutrition industry.⁴¹ Among dietary supplements, vitamins led the way in 2002 with \$6.2 billion in sales⁴², an increase of 3% over 2001.⁴³ According to a 1999 study, the average product price for a dietary supplement in the United States was \$17.15.⁴⁴

The dietary supplement industry has a market structure that encourages rapid growth. This is because the dietary supplement market, at least in terms of manufacturing, is not highly concentrated.⁴⁵ However, some submarkets, such as the vitamin market, are more concentrated.⁴⁶ There are few dominant brands in the dietary supplement industry and barriers to entry are not high.⁴⁷ This structure is changing though as the dietary supplement market consolidates and as new federal and industry regulations are issued.⁴⁸ This may lead to the rise of more identifiable dietary supplement brand names.⁴⁹

Along with rapid growth in dietary supplement sales, the distribution channels for dietary supplements have been changing. A 1999 report found that the market share of natural and health food stores was growing at a rate of 55% while the market share of multilevel marketing firms was falling.⁵⁰ Other distribution channels for dietary supplements include drugstores, mass merchandise outlets, mail order, the Internet, healthcare

³⁹See ECONOMIC CHARACTERIZATION, *supra* note 4, at 5-1.

⁴⁰See National Nutritional Foods Association, *supra* note 38. The nutrition industry is comprised of functional foods, supplements, natural and organic foods, and natural personal care products. *Id.*

⁴¹*Id.*

⁴²*Id.* Herbals were second with \$4.3 billion; sports nutrition took in \$1.8 billion and minerals took in \$1.5 billion. *Id.*

⁴³*Id.*

⁴⁴CENTER FOR ECONOMICS RESEARCH, RESEARCH TRIANGLE INSTITUTE, DIETARY SUPPLEMENT SALES INFORMATION 5-11 (Final Report 1999) [Hereinafter DIETARY SUPPLEMENT SALES INFORMATION].

⁴⁵ECONOMIC CHARACTERIZATION, *supra* note 4, at 5-14.

⁴⁶See *id.* at 5-15.

⁴⁷*Id.* at 5-16.

⁴⁸*Id.*

⁴⁹See *id.* at 6-17.

⁵⁰*Id.* at 5-11. Multilevel marketing firms consist of “direct selling, party plans, relationship selling, person-to-person selling, and network marketing.” *Id.*

practioners, and specialty shops.⁵¹

C. Dietary Supplement Use in the United States

The uses for dietary supplements are just as varied as the types of dietary supplements available. Some representative uses given by consumers are “to improve nutrition, to make up for uses missing in the food supply, to decrease susceptibility to or severity of disease, or to increase energy or improve performance.”⁵² Some supplements, frequently herbals and botanicals, are also taken as an alternative to conventional medicine.⁵³

The sports nutrition industry is an illustrative example of consumer dietary supplement use. In 2001, the sports supplement market accounted for \$1.74 billion in sales.⁵⁴ More broadly, the sports nutritional functional foods market (including nutrition bars and sports and energy drinks like Gatorade) accounted for \$4.3 billion in sales in 2001.⁵⁵ And in particular, the energy drink market (including both conventional foods and dietary supplements in liquid forms) increased 465% from 1998 to 2003, and it is predicted to grow by 210% from 2003 to 2008.⁵⁶

As to the prevalence of use of dietary supplements, according to a 1999 report, “two out of every five

⁵¹*Id.* at 5-9 to 5-13.

⁵²U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, USE OF DIETARY SUPPLEMENTS IN THE UNITED STATES, 1988-94 1 (1999) [Hereinafter DHHS Dietary Supplement Use].

⁵³*Id.*

⁵⁴Ohr, *supra* note 18, at 63 (citing NUTRITIONAL BUSINESS JOURNAL). The sports supplement market includes hardcore sports beverages, sports powders, and sports pills. *Id.* at 63.

⁵⁵*Id.* at 63.

⁵⁶*Energy*, *supra* note 21, at 56 (citing Mintel International Group, Ltd.). Energy drinks can contain a wide array of dietary supplements or ingredients that would otherwise be considered dietary supplements if the product was marketed as a dietary supplement. Examples include taruine, ginseng, carnitine, guarana, vitamins, minerals, herbs, protein and amino acids, creatine, and even hornet’s saliva. See Leslie Bonci, “*Energy*” Drinks: Help, Harm or Hype?, GATORADE SPORTS SCIENCE INSTITUTE, 15 SPORTS SCIENCE EXCHANGE 1, 2-3 (2002).

people in the U.S. were taking dietary supplements between 1988 and 1994.”⁵⁷ Among these users, females were more likely to use dietary supplement than males (44% compared to 35%),⁵⁸ and children age one to five were among the largest users of dietary supplements.⁵⁹ Further, among adults age twenty and older, dietary supplement use tended to increase with age.⁶⁰ Educational level and total family income were both positively related to dietary supplement use,⁶¹ and among regions of the country, people in the West were more likely (by at 10% margin) to take dietary supplements than people in any other region of the country.⁶² As to the amount of dietary supplements taken, just over two-thirds of dietary supplements users took only one supplement and of those single users, 46% took a vitamin or mineral combination product.⁶³ Overall what can be said of this and other similar studies is that “dietary supplement use is more common among older adults, women, white people, people living in the West, and those with higher incomes and levels of education.”⁶⁴

III. UNITED STATES REGULATION OF DIETARY SUPPLEMENTS

With this general background on dietary supplements in mind, this section now turns to a brief review of the history of notable dietary supplement regulation in the United States with a focus on the DSHEA and

⁵⁷DHHS Dietary Supplement Use, *supra* note 52, at 6. The study targeted the U.S. population of at least two months of age. *Id.* at 1.

⁵⁸*Id.* at 3.

⁵⁹*See id.* at 3-4. Use ranged from 42% to 51%. *Id.* at 3.

⁶⁰*Id.* at 3-4. Females age fifty and older had the highest percentage of dietary supplement use at over 55%. *See id.* at 4.

⁶¹*Id.* at 4.

⁶²*Id.*

⁶³*Id.* at 5. Generally, 47% of all dietary supplement users took a vitamin or mineral combination product. *Id.* Other heavily used supplements included “lecithin, garlic, ginseng, fiber, amino acids, protein drinks, and other performance-enhancing or body-building formulas.” *Id.* at 7.

⁶⁴*Id.* at 6. It should be noted that this study ended just as the federal government enacted the DSHEA. The study noted that the prevalence of dietary supplement use could change with passage of the DSHEA, as more scientific evidence accumulates supporting dietary supplement use, and as attitudes towards alternative medicine shift. *Id.* at 7. The ability of dietary supplement labels to now carry a variety of health claims (unqualified or qualified) certainly has had an impact on the prevalence of use. For more about dietary supplement health claims, *see* discussion *infra* Part III.C.5.

post-DSHEA regulation and other activity.⁶⁵

A. Pre-DSHEA Regulation

Regulation of dietary supplements is not a new phenomenon, and the DSHEA, while the most comprehensive legislation addressing dietary supplements, was not the first such legislation on the subject. The major pieces of legislation addressing dietary supplements prior to the DSHEA were the Food, Drug, and Cosmetic Act of 1938 (“FDCA”),⁶⁶ the 1976 addition of section 411 to the FDCA known as the Proxmire Amendment,⁶⁷ and the Dietary Supplement Act of 1992 (“DSA”).⁶⁸

1. The FDCA

The FDCA made the first legislative reference to dietary supplements. Specifically, section 403 of the FDCA (now codified at 21 U. S. C. § 343(j)) referenced food for special dietary use.⁶⁹ Further, dietary supplements were included in the category of food in section 201(f) of the FDCA (now codified at 21 U. S. C. § 321(f)).⁷⁰

The FDCA also included new provisions regarding drugs, and the FDA quickly utilized these provisions to

⁶⁵This review is not meant to be comprehensive. It focuses on notable dietary supplement statutory, regulatory, and industry activity in order to convey an accurate record of dietary supplement regulation in the United States.

⁶⁶Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U. S. C. § 301 et seq.).

⁶⁷Pub. L. No. 94-278, 90 Stat. 401 (1976) (codified at 21 U. S. C. § 350).

⁶⁸Pub. L. No. 102-571, 106 Stat. 4491 (1992).

⁶⁹This provision provided that a food for special dietary use would be considered misbranded unless its “label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.” 21 U. S. C. § 343(j). “Secretary,” here and in all other references in the paper, refers to the Secretary of Health and Human Services. *See* 21 U. S. C. § 321(d).

⁷⁰This section defined food as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.” Dietary supplements thus would have fallen under 21 U. S. C. § 321(f)(3); however, under the FDCA a dietary supplement would also have been considered a food additive unless it was a substance that was Generally Recognized as Safe (“GRAS”), or it had prior sanctioned status. JAMES L. VETTER, PH.D, FOOD LAWS AND REGULATIONS 153 (1996). Thus, if the dietary supplement was not GRAS or did not have prior sanctioned status, it would have had to comply with the food additive provisions of the FDCA. *See* discussion *infra* Part III.B.2 on dietary supplements, GRAS, and food additive provisions under the DSHEA.

sweep certain food products, including certain dietary supplements, under these more stringent drug provisions.⁷¹ Several cases during this time hinged on the claims made on the label of such dietary supplements or the literature accompanying them.⁷²

In the decades following enactment of the FDCA, the FDA passed several regulations pertaining to dietary supplements. In 1941 the FDA promulgated the first recommended daily allowance (“RDA”) regulations for vitamin and mineral supplements and other foods for special dietary use containing added vitamins or minerals.⁷³ In 1962 the FDA published a proposed notice that “only those nutrients recognized by ‘competent authorities’ as essential and of significant human value could be offered for sale.”⁷⁴ Due to heavy pressure by the dietary supplement industry, this proposal never went into effect.⁷⁵ New regulations concerning labeling and content of special dietary food products were proposed in 1966⁷⁶ and were promulgated in final form in 1973.⁷⁷ These regulations classified most vitamins and minerals as drugs if they exceeded certain levels of potency (based on RDAs) and also limited the sale of vitamin and mineral combination products.⁷⁸

2. The Proxmire Amendment

Stemming from FDA action in the 1960s and early 1970s concerning dietary supplement vitamin and mineral

⁷¹I. SCOTT BASS & ANTHONY L. YOUNG, DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT: A LEGISLATIVE HISTORY AND ANALYSIS 9 (1996).

⁷²See *id.* at 9-11 (contains a discussion of these cases).

⁷³6 Fed. Reg. 5921-5926 (1941). See COMMISSION ON DIETARY SUPPLEMENT LABELS, REPORT OF THE COMMISSION ON DIETARY SUPPLEMENT LABELS (Final Report 1997) 11 [hereinafter CDSL Report]. The regulations placed no limit on the amount or type of nutrients that could be included in such supplements. CDSL Report *supra*.

⁷⁴BASS, *supra* note 71, at 11 (citing 27 Fed. Reg. 5815, 5817 (June 20, 1962)).

⁷⁵*Id.* at 11.

⁷⁶31 Fed. Reg. 8521, 8526 (June 18, 1966).

⁷⁷38 Fed. Reg. 20,730, 20,732 (Aug. 2, 1973). The FDA proposed that all vitamin and mineral supplements bear the following disclaimer: “[v]itamins and minerals are supplied in abundant amounts by commonly available foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements.” 31 Fed. Reg. 15,730-15,736 (1966); see CDSL Report, *supra* note 73, at 11. This proposed rule was not included in the final rulemaking. In addition, the final rulemaking was subject to much FDA and court revision and was finally revoked in its entirety. See CDSL Report, *supra* note 73, at 12.

⁷⁸38 Fed. Reg. 20,730, 20,732 (Aug. 2, 1973).

potency, Congress took action in 1976. Unsatisfied with FDA regulations regarding vitamin and mineral potency, Congress responded with the Proxmire Amendment.⁷⁹ The Proxmire Amendment added section 411 to the FDCA (now codified at 21 U. S. C. § 350) and negated the FDA's 1973 regulations concerning vitamin and mineral potency. The Proxmire Amendment prohibited the FDA from placing maximum limits of potency on vitamins or minerals within a food,⁸⁰ invalidated the FDA's authority to classify a vitamin or mineral as a drug based on potency,⁸¹ and permitted vitamins and minerals to be sold in many forms, including combinations, within a food.⁸² The effect of the Proxmire Amendment was to limit the FDA's authority to regulate dietary supplements, at least when they contained vitamins or minerals.⁸³

After the Proxmire Amendment, the FDA mostly abandoned its efforts to regulate dietary supplements under FDCA drug provisions and instead turned to FDCA food additive provisions.⁸⁴ The FDA's theory was that dietary supplements could be attacked as unsafe food additives. By 1992, U.S. courts of appeal rejected this theory at least regarding non-combination dietary supplements.⁸⁵

3. The DSA

The next major governmental action regarding dietary supplements came when Congress passed the Nutrition

⁷⁹Pub. L. No. 94-278, 90 Stat. 401 (1976) (codified at 21 U. S. C. § 350). In an eight month span in 1973 approximately seventy bills were introduced in Congress seeking to limit the FDA's regulation of vitamin and mineral potency. BASS, *supra* note 71, at 12. The Proxmire Amendment was the final result.

⁸⁰Pub. L. No. 94-278, 90 Stat. 401 (1976) (codified at 21 U. S. C. § 350(a)(1)(A)). For purposes of 21 U. S. C. § 350, the term food means "food for humans which is a food for special dietary use which is or contains any natural or synthetic vitamin or mineral, and which is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or if not intended for ingestion in such a form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet." 21 U. S. C. § 350(c)(1) (as amended by the DSHEA).

⁸¹Pub. L. No. 94-278, 90 Stat. 401 (1976) (codified at 21 U. S. C. § 350(a)(1)(B)).

⁸²*Id.* (codified at 21 U. S. C. § 350(a)(1)(C)).

⁸³After the Proxmire Amendment, no formal dietary supplement labeling provisions were in effect until 1994. CDSL Report, *supra* note 73 at 12. However, most dietary supplement manufacturers informally followed the FDA's 1973 regulations. *Id.*

⁸⁴The statutory provision regarding food additives is 21 U. S. C. § 348. Basically, the FDCA requires premarket approval for food additives that are not prior sanctioned, GRAS, or the subject of a food additive regulation.

⁸⁵*See* United States v. Two Plastic Drums, 985 F.2d 814 (7th Cir. 1993); United States v. 29 Cartons, 987 F.2d 33 (1st Cir. 1993). Such non-combination dietary supplements thus were considered conventional food not subject to the food additives provision. However, the FDA and some courts then took the position that dietary supplements, except vitamins and minerals with a recognized nutritional value, were not considered conventional food. *See* Nutrilab v. Schweiker, 713 F.2d 335 (7th Cir. 1983); American Health Prod. Co. v. Hayes, 744 F.2d 912 (2d Cir. 1984); BASS, *supra* note 71, at 15.

Labeling and Education Act of 1990 (“NLEA”).⁸⁶ The NLEA provided foods, including dietary supplements, to bear nutritional labeling.⁸⁷ Further, the NLEA created a health claim approval system for the FDA including the availability of separate procedures for dietary supplement health claims.⁸⁸ However, the FDA failed to implement any separate NLEA health claim procedures for dietary supplements except to a very limited extent.⁸⁹

The dietary supplement provisions of the NLEA were to be implemented by the FDA through publication of proposed and final rules, but as the FDA carried out this implementation,⁹⁰ Congress passed the DSA. The DSA instituted a one-year moratorium on implementation of dietary supplement labeling under the NLEA with certain exceptions for health claims.⁹¹ New proposed regulations covering dietary supplement labeling were to be issued by June 15, 1993 with final regulations due by the end of that year.⁹² While the FDA worked to comply with these dates,⁹³ Congress passed the DSHEA, drastically reshaping dietary supplement regulation.

B. The Dietary Supplement Health and Education Act of 1994

Due in part to “the importance of nutrition and the benefits of dietary supplements to health promotion and

⁸⁶Pub. L. No. 101-535, 104 Stat. 2352 (1990) (codified in scattered section of 21 U. S. C.).

⁸⁷*Id.* (codified at 21 U. S. C. § 343).

⁸⁸*Id.* (codified at 21 U. S. C. § 343(r); BASS, *supra* note 71, at 15.

⁸⁹BASS, *supra* note 71, at 15.

⁹⁰For example, the FDA published proposed health claim regulations for dietary supplements in 1991. 56 Fed. Reg. 60,537 (Nov. 27, 1991).

⁹¹Pub. L. No. 102-571, § 202, 106 Stat. 4491 (1992).

⁹²*Id.*

⁹³The FDA issued an advance notice of proposed rulemaking concerning dietary supplement in June 1993. 58 Fed. Reg. 33,690 (June 18, 1993).

disease prevention” and the increasing reliance of consumers on dietary supplements,⁹⁴ Congress passed the DSHEA in 1994.⁹⁵ The DSHEA created a new structure for regulation of dietary supplements by making dietary supplements a new category of regulation within the framework of food and apart from drugs. This was a drastic departure from previous decades of regulation. The DSHEA enacted the following main provisions: (1) definitions of dietary supplements and dietary ingredients;⁹⁶ (2) dietary supplement safety provisions;⁹⁷ (3) certain dietary supplement labeling exemptions;⁹⁸ (4) statements of nutritional support for dietary supplements;⁹⁹ (5) dietary supplement labeling requirements;¹⁰⁰ (6) regulations pertaining to new dietary ingredients;¹⁰¹ (7) dietary supplement good manufacturing practices;¹⁰² (8) revocation of the FDA’s advance notice of proposed rulemaking under the DSA;¹⁰³ (9) establishment of a Commission on Dietary Supplement Labels;¹⁰⁴ and (10) establishment of the Office of Dietary Supplements.¹⁰⁵

1. Dietary Supplement Definitions

The DSHEA defined dietary supplements as food,¹⁰⁶ thus ending previous decades of controversy over whether dietary supplements should be fit into the existing food or drug frameworks. Specifically, the

⁹⁴Pub. L. No. 103-417, § 2, 108 Stat. 4325 (1994).

⁹⁵Pub. L. No. 103-417, 108 Stat. 4325 (1994) (codified as amended in scattered sections of 21 U. S. C.).

⁹⁶*Id.* § 3 (codified at 21 U. S. C. §§ 321(ff), 321(s)(6), 350(c)(1)(B)). The DSHEA also amended the definition of drug. *Id.* at § 10 (codified at 21 U. S. C. § 321(g)(1)).

⁹⁷*Id.* § 4 (codified at 21 U. S. C. § 342(f)).

⁹⁸*Id.* § 5 (codified at 21 U. S. C. § 343-2).

⁹⁹*Id.* § 6 (codified at 21 U. S. C. § 343(r)(6)).

¹⁰⁰*Id.* § 7 (codified at 21 U. S. C. §§ 343(s), 343(q)(5)(F), 343(r)(2)(F), 350(b)(2)); *see also id.* at § 10 (codified at 21 U. S. C. § 343(s)).

¹⁰¹*Id.* § 8 (codified at 21 U. S. C. § 350b).

¹⁰²*Id.* § 9 (codified at 21 U. S. C. § 342(g)).

¹⁰³*Id.* § 11.

¹⁰⁴*Id.* § 12.

¹⁰⁵*Id.* § 13 (codified at 42 U. S. C. § 287c-11).

¹⁰⁶*Id.* § 3 (codified at 21 U. S. C. § 321(ff)). This definition does not apply for purposes of 21 U. S. C. § 321(g) (the FDCA definition of drug). This preserved the FDA’s ability to deem a dietary supplement a drug if the dietary supplement makes certain claims. Certain dietary supplements can also be considered drugs under 21 U. S. C. § 321(ff)(3). Dietary supplements are excluded from the definition of drugs based on certain health or structure/function claims made on the label in compliance with other sections of the FDCA. 21 U. S. C. § 321(g)(1)(D).

DSHEA created a new category of food and then defined this category by the inclusion of the specific dietary ingredients of vitamins, minerals, herbs or botanicals, amino acids, any substances consumed to supplement the diet, or concentrates, metabolites, constituents, extracts, or combinations thereof.¹⁰⁷ The DSHEA also stated that dietary supplements must be intended for ingestion in tablet, capsule, powder, soft gel, or liquid form.¹⁰⁸ Further, if the dietary supplement is not intended for ingestion in such form, it must not be represented as conventional food and must not be represented as meal replacement.¹⁰⁹ Further, the dietary supplement, no matter the form, must not be represented for use as conventional food and must not be represented as meal replacement.¹¹⁰ Additionally all dietary supplements must be labeled as a dietary supplement.¹¹¹

The significance of the new definitions for dietary supplements cannot be understated. These provisions mean that dietary supplements, like all other foods, are classified based on the intended use of such products as demonstrated by label claims, advertising, or product statements.¹¹² Even though the DSHEA specifies certain types of dietary supplements and the forms such supplements must take, the DSHEA allows dietary supplements to be sold in conventional food form so long as they are not represented as conventional food or as meal replacement and so long as they are labeled as dietary supplements.¹¹³

The DSHEA also took the monumental step of excluding dietary supplements and dietary ingredients in-

¹⁰⁷Pub. L. No. 103-417, § 3 (codified at 21 U. S. C. § 321(ff)); *see supra* Part II.A for a discussion of types of dietary supplements.

¹⁰⁸*Id.* (codified at 21 U. S. C. §§ 321(ff)(2)(A)(i), 350(c)(1)(B)(i)).

¹⁰⁹*Id.* (codified at 21 U. S. C. §§ 321(ff)(2)(A)(ii), 350(c)(1)(B)(ii)).

¹¹⁰*Id.* (codified at 21 U. S. C. § 321(ff)(2)(B)).

¹¹¹*Id.* (codified at 21 U. S. C. § 321(ff)(2)(C)).

¹¹²*See* DENTALI, *supra* note 13, at 89.

¹¹³21 U. S. C. §§ 321(ff)(2)(B)-(C), 350(c)(1)(B)(ii).

tended for use in dietary supplements from the definition of food additives,¹¹⁴ thus clearing up decades of controversy on that subject.

The exclusion of dietary supplements from the FDCA food additive provisions also cannot be understated. Because dietary supplements are now excluded from the FDCA food additive provisions, dietary supplements cannot be deemed adulterated under food additive provisions of the FDCA. All dietary supplements thus bypass the need to receive specific approval from the FDA for use as food additives.¹¹⁵ Dietary supplements also bypass the need to be Generally Recognized as Safe (“GRAS”) by the FDA or the food industry.¹¹⁶ And notably, by virtue of being excluded from the definition of food additives, dietary supplements do not have to comply with the DeLaney Clause prohibiting the FDA from approving food additives that have been “found to induce cancer when ingested by man or animal.”¹¹⁷

¹¹⁴*Id.* (codified at 21 U. S. C. § 321(s)(6)).

¹¹⁵Food additive provisions of the FDCA are codified at 21 U. S. C. § 342. New dietary ingredients, however, must be approved by the FDA otherwise the dietary supplement will be considered adulterated. *See* discussion *infra* Part III.B.6. As to the food additive provisions, the process avoided is an onerous one. A brief account of the food additive process is as follows: the dietary supplement manufacturer must (1) file a food additive petition, (2) conduct scientific data review regarding the food additive, and (3) fulfill criteria of the FDA. GEORGE A. BURDOCK, *The GRAS Process*, FOOD TECHNOLOGY, May 2003, at 17. The FDA must then (1) issue a proposed rule regarding the food additive petition for notice and comment and (2) issue a final rule regarding the food additive petition in the Federal Register. BURDOCK, *supra*.

¹¹⁶Food additives must either be GRAS or have prior sanctioned status by the FDA from before 1958, otherwise such ingredients are considered food additives and subject to food additive provisions. *See* Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958) (codified at 21 U. S. C. §§ 342(a)(2)(C), 348, 321(s)). To have prior sanctioned status, the food ingredient could not have been a drug or herbal remedy and must have been used by a significant number of people before 1958. BURDOCK, *supra* note 115. If a food ingredient is GRAS for its intended use, then it may be used without seeking specific approval from the FDA. However, for an ingredient to be GRAS, it must have been found safe through a series of scientific tests and information. Specifically, for a substance to be GRAS

“there must be reasonable certainty in the minds of scientist that is it not harmful under its conditions of intended use; the data and information to establish this conclusion must be publicly available; and there must be a basis to conclude that there is consensus among qualified experts about the safety of the substance for its intended use.”

ANTHONY A. ANSCOMBE, *Regulating Botanicals in Food*, FOOD TECHNOLOGY, Jan. 2003, at 18. This procedure is, like the food additive procedures, an onerous one. The basic framework is as follows: the dietary supplement manufacturer must (1) have a well prepared and researched substance, (2) have a technical use and purpose for the substance, (3) have documentation regarding to what the substance is to be added and at what levels, (4) review the published literature and data concerning the substance, (5) develop any needed data, (6) compile all of this information and data into a GRAS monograph, (7) have the GRAS monograph reviewed by an independent expert panel which must produce a consensus statement regarding the GRAS status of the substance, and (8) optionally notify the FDA. JAMES T. HEIMBACH, *GRAS Determination: A Short Guide*, PREPARED FOODS, Jan. 2003, 123, 123-129.

¹¹⁷21 U. S. C. § 348(c)(3)(A). Dietary supplements containing color additives must still comply with the DeLaney Clause. 21 U. S. C. § 379e(b)(5)(B)(i).

The new dietary supplement definition and the exclusion of dietary supplements from food additive provisions mean that the manner in which a product's intended use (conventional food versus dietary supplement) has an enormous impact on the regulatory process. For example, the DSHEA, under the new dietary supplement provisions, grandfathered in many botanicals that do not have to undergo a new dietary ingredient procedure.¹¹⁸ These botanicals thus may be used in dietary supplements without regulatory hassle; however, many of these same botanicals were not grandfathered in by the Food Additives Amendment of 1958 and thus would either have to be GRAS or undergo the onerous food additive approval process. Thus, a company wishing to introduce such a botanical could save significant time and money by introducing the botanical as a dietary supplement rather than a conventional food or ingredient in a conventional food.¹¹⁹ However, dietary supplement procedures are not always the easier approach. For example, McNeil Consumer Healthcare sought to introduce Benecol, a canola oil margarine substance that contains cholesterol-lowering herbals or botanicals (specifically sitostanol esters), into the U.S. market as a dietary supplement.¹²⁰ McNeil figured this would present the lowest regulatory hurdles; however, the FDA rejected Benecol as a dietary supplement.¹²¹ The chief reason for rejection was that Benecol was represented as a conventional food.¹²² The FDA further held that the sitostanol esters were unapproved food additives and not GRAS, though McNeil was able to later demonstrate GRAS status and Benecol was approved as a conventional food.¹²³ An additional example demonstrates the malleability of the dietary supplement/conventional food distinction. The FDA and the Herbal Products Association have recently been in disagreement over whether juice

¹¹⁸Pub. L. No. 103-417, § 8 (codified at 21 U. S. C. § 350b); DENTALI, *supra* note 13, at 92.

¹¹⁹This is particularly true because botanicals have not generally undergone large scale safety studies or accumulated other relevant scientific data which would be useful for GRAS determination of the food additive approval process. ANSCOMBE, *supra* note 116, at 17.

¹²⁰DENTALI, *supra* note 13, at 92.

¹²¹*Id.*

¹²²The statement of identity listed Benecol as a butter or margarine replacement that would help manage cholesterol levels naturally through food consumption. *Id.*

¹²³*Id.* As an additional example, The Hain Foods Group, Inc., tried to introduce a line of soups containing Echinacea and St. John's Wart as dietary supplements. *Id.* The FDA rejected this use stating that labeling which contained the word "soup," pictures of soup, and references to conventional foods found in soup served to represent the product as conventional food. *Id.* Further, the FDA stated that both Echinacea and St. John's Wart were unapproved food additives that had yet to be demonstrated GRAS. *Id.*

beverages including herbal ingredients may be represented as dietary supplements. In 2000 and 2001 the FDA sent warning letters to several juice manufactures alleging that the presence of certain herbal ingredients in their juice beverages constituted adulteration.¹²⁴ These juice beverages were marketed as conventional foods and thus the FDA treated the herbal ingredients in the beverages as unapproved food additives.¹²⁵ The FDA did acknowledge, however, that dietary supplements could be marketed in beverage form similar to conventional food so long as the labeling was accurate and the dietary supplement was not represented for use as conventional food.¹²⁶

2. Dietary Supplement Safety

Because under the DSHEA dietary supplements are considered food not subject to food additive provisions, dietary supplements are generally considered safe under the FDCA unless proven otherwise by the FDA. To prove that a conventional food is unsafe, the FDA must follow the statutory adulteration provisions.¹²⁷ However, the DSHEA created new standards by which to judge dietary supplement safety.¹²⁸ Under the DSHEA, a dietary supplement (or any food containing a dietary ingredient) is deemed adulterated if any one of four conditions is met. First, a dietary supplement is deemed adulterated if it “presents a significant or unreasonable risk of illness or injury under – (i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.”¹²⁹ Second, a dietary supplement is deemed adulterated if it “is a new dietary ingredient for which there

¹²⁴*Id.* at 94.

¹²⁵*Id.*

¹²⁶*Id.* Thus, the FDA has allowed calcium based dietary supplements to be sold as confectionary “chews.” *Id.* In general though, the FDA is of the opinion that standardized food beverage names and terms like “spring water,” “orange juice,” “drink” or “beverage” cannot appear on the label of a dietary supplement. *Id.*

¹²⁷21 U. S. C. § 342.

¹²⁸Pub. L. No. 103-417, § 4 (codified at 21 U. S. C. § 342(f)).

¹²⁹21 U. S. C. § 342(f)(1)(A).

is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.”¹³⁰ Third, a dietary supplement is deemed adulterated if it “pose[s] an imminent hazard to public health or safety.”¹³¹ Finally, a dietary supplement is deemed adulterated if it meets a conventional food adulteration standard in the FDCA “under the conditions of use recommended or suggested in the labeling of such dietary supplement.”¹³²

The DSHEA exemption of dietary supplements from all but one conventional food adulteration standard in the FDCA was a monumental change. Before the DSHEA, dietary supplements and dietary ingredients were held to all the conventional food adulteration standards under 21 U. S. C. § 342. This meant that before the DSHEA, a dietary supplement was deemed adulterated if

¹³⁰21 U. S. C. § 342(f)(1)(B).

¹³¹21 U. S. C. § 342(f)(1)(C).

¹³²21 U. S. C. § 342(f)(1)(D). Specifically, the dietary supplement must meet the adulteration standard under 21 U. S. C. § 342(a)(1). Section 342(a)(1) states that a food is deemed adulterated “[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.”

- (1) it bore or contained “any poisonous or deleterious substance which... [could have] render[ed] it injurious to health,”¹³³
- (2) in the case of a dietary supplement that contained no added substances (that is, it was not considered a combination product or it contained only naturally occurring ingredients), if the amount of such substance was considered unsafe within the meaning of other statutory language,¹³⁴
- (3) it bore or contained a “pesticide chemical residue that [wa]s unsafe” within the meaning of other statutory language¹³⁵
- (4) it bore or contained a food additive that was unsafe within the meaning of the Food Additive Amendment of 1958,¹³⁶
- (5) its composition or packaging met certain filth standards,¹³⁷
- (6) it was the product of a diseased animal or of an animal that had died other than by slaughter,¹³⁸
- (7) its container included “any poisonous or deleterious substance which... [could have] render[ed] the contents injurious to health,”¹³⁹
- (8) it had been intentionally exposed to radiation not approved by other statutory language,¹⁴⁰
- (9) it had been adulterated in an economic sense,¹⁴¹
- (10) it bore or contained a color additive deemed unsafe under other statutory language,¹⁴² or
- (11) it met certain special confectionary or oleomargarine adulteration provisions.¹⁴³

But after the DSHEA, all of these provisions (save for those listed in (1) and (2) above) were wiped clean and replaced with more limited provisions.¹⁴⁴ Combined with the exclusion of dietary supplements from

¹⁴⁴Even though the adulteration provisions under 21 U. S. C. § 342(a)(1) are applied to dietary supplements, they have been narrowed for dietary supplements by 21 U. S. C. § 342(f)(1)(D) to look only at recommended or suggested conditions of use.

food additive provisions, the dietary supplement industry faced vastly fewer regulatory hurdles than faced with conventional food.

The DSHEA went even further in its revisions of dietary supplement safety by placing the burden of proof on the government to demonstrate that a dietary supplement is adulterated.¹⁴⁵ No longer did dietary supplement manufacturers have to prove that a supplement was safe, rather the FDA had to prove the dietary supplement unsafe. This brought dietary supplement safety enforcement in line with the conventional foods, which are presumed to be safe unless the FDA proves otherwise, rather than drugs, which must be proven by manufacturers to be safe and efficacious. Further, the DSHEA laid out certain legal procedures that were to be followed concerning dietary supplement safety enforcement, in effect removing some FDA power over administrative review of dietary supplements.¹⁴⁶

3. Dietary Supplement Labeling Exemptions

The DSHEA made clear what did and did not constitute labeling for a dietary supplement. Under the DSHEA,

[a] publication, including an article, a chapter in a book, or an official abstract of a

¹⁴⁵Pub. L. No. 103-417, § 4 (codified at 21 U. S. C. § 342(f)(1)).

¹⁴⁶Specifically, when in court on any issue under 21 U. S. C. § 342(f)(1), such issue is to be decided de novo by the court rather than by deferring to FDA interpretation. *Id.* Additionally, before the government takes action in the form of a civil proceeding concerning dietary supplements under 21 U. S. C. § 342(f)(1)(A), the adverse party must receive proper notice and an opportunity to be heard. 21 U. S. C. § 342(f)(2).

peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary

supplement to consumers when it—

- (1) is not false or misleading;
- (2) does not promote a particular manufacturer or brand of a dietary supplement;
- (3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;
- (4) if displayed in an establishment, is physically separate from the dietary supplements; and
- (5) does not have appended to it any information by sticker or any other method.¹⁴⁷

This section cleared up years of prior FDA regulations regarding which types of publications carried in stores selling dietary supplements could be considered labeling under the FDCA and thus subject to labeling regulation.¹⁴⁸ Specifically, this section limited the FDA’s ability to regulate books and other publications as dietary supplement labeling by defining the exact conditions needed to avoid being considered labeling. In addition, the DSHEA made clear the right of a retailer or wholesaler of dietary supplements to sell books or other publications as part of their business regardless of the new DSHEA labeling exemptions.¹⁴⁹ Finally, the DSHEA put the burden of proof on the government concerning any proceeding brought under the new DSHEA labeling exemptions.¹⁵⁰ Thus, as with the exclusion of dietary supplements from food additive provisions, definition as drugs, and many of the conventional food adulteration provisions, the trend of

¹⁴⁸Specifically, 21 U. S. C. § 321(m) states that “[t]he term ‘labeling’ means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” If the term “labeling” applies than the labeling sections of the FDA apply. *See, e.g.*, 21 U. S. C. §§ 343, 350. The FDA had used 21 U. S. C. § 321(m) and accompanying labeling provisions of the FDCA to restrict books and other publications sold in stores also selling dietary supplements. For a discussion of this prior FDA activity, *see* BASS, *supra* note 71, at 49-50. Briefly, in the decades before the DSHEA, courts, including the U.S. Supreme Court, had upheld the FDA’s broad reading of what constituted labeling under 21 U. S. C. § 321(m). BASS, *supra* note 71, at 49.

¹⁴⁹Pub. L. No. 103-417, § 5 (codified at 21 U. S. C. § 343-2(b)).

¹⁵⁰*Id.* (codified at 21 U. S. C. § 343-2(c)).

relaxed dietary supplement regulation continued in this section.

4. Statements of Nutritional Support

The DSHEA took the significant step of allowing dietary supplement labeling and packaging to contain certain statements of nutritional support unavailable to conventional foods by expanding the realm of such statements.¹⁵¹ Specifically, the DSHEA allowed a statement of nutritional support on the label of dietary supplements without the dietary supplement being deemed misbranded if

the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient.¹⁵²

Thus dietary supplements could make classical nutrient deficiency disease statements, claims about structure or function, and general well-being statements (together referred to as statements of nutritional support or structure/function claims). Even before the DSHEA, structure/function claims for nutrients in conventional foods were excluded from the definition of a drug.¹⁵³ Such claims could be made without notifying the FDA and without being deemed drug claims if they “concerned a non-disease-related effect on the structure or function of the body and the claimed effect derived from a food attribute, such as nutritive value.”¹⁵⁴ If the claims linked a nutrient to a disease or a health-related condition (so called “health claims” rather than structure/function claims), these were also allowed before the DSHEA but required authorization by specific FDA regulation.¹⁵⁵ What the DSHEA accomplished was to provide expanded safe harbor from

¹⁵¹This modifies the NLEA amendments, Pub. L. No. 101-535, 104, Stat. 2352 (1990) (codified as amended at 21 U. S. C. § 343(r)), to the FDCA for dietary supplements.

¹⁵³21 U. S. C. § 321(g)(1)(C).

¹⁵⁴65 Fed. Reg. 999, 1001 (Jan. 6, 2000). The FDA allowed, and still allows, traditional structure/function claims (such as “calcium builds strong bones”) to be made for conventional foods. BASS, *supra* note 71, at 56.

¹⁵⁵21 U. S. C. § 343(r)(1)(B), (r)(3), (r)(5)(D). For a more detailed discussion of pre-DSHEA regulation of structure/function

drug provision for statements of nutritional support made on dietary supplements concerning nutrients and dietary ingredients.¹⁵⁶ The DSHEA also ensured that complying with these statements of nutritional support provisions would not lead to a dietary supplement being deemed a drug.¹⁵⁷

The DSHEA also required that a manufacturer of a dietary supplement containing a statement of nutritional support on its label must have “substantiation that such statement is truthful and not misleading.”¹⁵⁸ And the DSHEA further required that the label contain the following disclaimer: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”¹⁵⁹ Finally, the DSHEA made clear that a dietary supplement shall not “claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.”¹⁶⁰

5. Dietary Supplement Labeling

The DSHEA enacted significant changes to dietary supplement labeling.¹⁶¹ First, the label of a dietary supplement must list the name of each ingredient and the quantity of such ingredient.¹⁶² Second, the label must

claims and other health related claims, *see* BASS, *supra* note 71, at 56-58. After passage of the Food and Drug Administration Modernization Act of 1997 (“FDAMA”), Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified at 21 U. S. C. § 343(r)), such health claims, if based on an authoritative statement, could also be made without pre-authorization by the FDA.

¹⁵⁶Premarket approval is not permitted nor can it be required for such claims. The Statement of Agreement to the DSHEA specifically confirms this. 140 CONG. REC. H11179 (daily ed. Oct. 6, 1999). However, while the DSHEA provision do not require premarket approval nutrient content claims, the FDA must be notified within thirty days of marketing a dietary supplement making a claim under this provision. 21 U. S. C. § 343(r)(6)(C). This is a significant departure from traditional claims for drugs, all of which must receive prior approval from the FDA. *See* 21 U. S. C. § 355.

¹⁵⁷Pub. L. No. 103-417, § 10 (codified at 21 U. S. C. § 321(g)(1)(D)). This amended the definition of drug under the FDCA.

¹⁵⁸*Id.* § 6 (codified at 21 U. S. C. § 343(r)(6)(B)).

¹⁵⁹*Id.* (codified at 21 U. S. C. § 343(r)(6)(C)).

¹⁶⁰*Id.* This serves as a line of demarcation between dietary supplements and drugs and their respective claims.

¹⁶¹All dietary supplement labels were required to meet these specifications after December 31, 1996. *Id.* § 7.

¹⁶²*Id.* (codified at 21 U. S. C. § 343(s)(2)). If the dietary supplement contains a proprietary blend of ingredients, then the label need only list the total quantity of all ingredients in the blend. *Id.* (codified at 21 U. S. C. § 343(s)(2)(A)(ii)(II)). If the dietary supplement contains an herbal or botanical, then the label must identify “any part of the plant from which the ingredient is derived.” *Id.* (codified at 21 U. S. C. § 343(s)(2)(C)).

bear the term “dietary supplement.”¹⁶³ Finally, if the dietary supplement is “covered by the specifications of an official compendium,” it must meet these specifications if the dietary supplement represents that it conforms to such specifications.¹⁶⁴ If the dietary supplement is not covered by an official compendium, it must contain the identity and strength that it is represented to have,¹⁶⁵ and it must contain the quality, purity, and compositional specifications that it is represented to have.¹⁶⁶

The DSHEA also amended the FDCA (as amended by the NLEA) nutritional labeling and content claims for dietary supplements. Dietary supplements must include nutrition information “in a manner which is appropriate for the product.”¹⁶⁷ Specifically, ingredients present in a dietary supplement in a significant amount and for which there is a recommendation for daily consumption (a recommended daily intake (“RDI”) or daily reference value (“DRV”)) must be listed first on the nutrition label.¹⁶⁸ More importantly, the DSHEA then required all other dietary ingredients present to be listed in the nutrition label even if they had no RDI or DRV.¹⁶⁹ Before the DSHEA, the FDA did not allow such a listing.¹⁷⁰ Further, the nutritional label must include the quantity of each listed ingredient per serving.¹⁷¹ Finally, the nutrition label may include the source of a dietary ingredient, nutrition information must precede ingredient statements on the label, and if

¹⁶³*Id.* (codified at 21 U. S. C. § 343(s)(2)(B)). The term “dietary supplement” may be modified by the name of an included ingredient. *Id.*

¹⁶⁴*Id.* (codified at 21 U. S. C. § 343(s)(2)(D)). The U.S. Pharmacopoeia is an example of an official compendium.

¹⁶⁵*Id.* (codified at 21 U. S. C. § 343(s)(2)(E)(ii)(I)).

¹⁶⁶*Id.* (codified at 21 U. S. C. § 343(s)(2)(E)(ii)(II)).

¹⁶⁷*Id.* (codified at 21 U. S. C. § 343(q)(5)(F)).

¹⁶⁸*Id.* (codified at 21 U. S. C. § 343(q)(5)(F)(i)). If such an ingredient is not present in a significant amount, it need not be listed. *Id.* This is also a change from FDA regulations for conventional food which require foods to list certain nutrition information ingredients regardless of their presence in the food. 21 U. S. C. § 343(q)(1)(D); 21 C. F. R. § 101.9. As to what constitutes a “significant amount” for dietary supplement nutritional label listing, see 58 Fed. Reg. 361 (Jan. 4, 1994) (implementing NLEA dietary supplement labeling).

¹⁶⁹Pub. L. No. 103-417, § 7 (codified at 21 U. S. C. § 343(q)(5)(F)(i)).

¹⁷⁰Specifically, such substances could not be included in the Nutrition Facts Box of the label. 21 C. F. R. § 101.9(c) (1995). Conventional foods still must adhere to this rule.

¹⁷¹Pub. L. No. 103-417, § 7 (codified at 21 U. S. C. § 343(q)(5)(F)(ii)). This section also applied to proprietary blends of ingredients. *Id.*

a dietary ingredient is listed with the nutrition information it need not also be listed with the statement of ingredients.¹⁷²

The DSHEA also made several other changes for dietary supplement nutrition labeling. First, a dietary supplement label may contain percentage-level claims for which there is no RDI or DRV without being deemed misbranded.¹⁷³ Second, the DSHEA placed all dietary supplements within the Proxmire Amendment's provision that listing dietary ingredients on the label with other conventional food ingredients will not cause a dietary supplement to be deemed misbranded so long as all ingredients are listed and proper regulations are followed.¹⁷⁴ Finally, the DSHEA made clear that a "dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings."¹⁷⁵

6. New Dietary Ingredients

As a tradeoff for excluding dietary supplements from the onerous food additive provisions and GRAS provisions of the FDCA, the DSHEA enacted specific safety provisions for substances considered new dietary ingredients. Under the DSHEA, a new dietary ingredient is "a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994."¹⁷⁶ Thus, all dietary supplements in use before October 15, 1994 are grandfathered in and need only meet the new, limited adulteration standards for all dietary supple-

¹⁷²*Id.* (codified at 21 U. S. C. § 343(q)(5)(F)(iii)-(iv)).

¹⁷³*Id.* (codified at 21 U. S. C. § 343(r)(2)(F)).

¹⁷⁴*Id.* (codified at 21 U. S. C. § 350(b)).

¹⁷⁵*Id.* §10 (codified at 21 U. S. C. § 343(s)).

¹⁷⁶*Id.* § 8 (codified at 21 U. S. C. § 350b(c)).

ments.¹⁷⁷ However, a dietary supplement containing a new dietary ingredient shall be deemed adulterated under these new adulteration standards for all dietary supplements unless “[t]he dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.”¹⁷⁸ Thus, dietary supplements containing only chemically unaltered ingredients from conventional foods are excluded from the definition of new dietary ingredient. If the above condition is not met, a dietary supplement containing a new dietary ingredient can still avoid being deemed adulterated if

[t]here is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.¹⁷⁹

With this subsection, the DSHEA enacted a notification provision which manufacturers of new dietary ingredients must follow. This is a notifications provision only, and it does not require, as with drugs, premarket approval from the FDA. Further, if a dietary supplement manufacturer does not want to follow this notification provision for new dietary ingredients, the DSHEA allows such manufacturer to, in the alternative, petition the FDA for “issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe.”¹⁸⁰ The Secretary must then rule on the petition within 180 days of filing.¹⁸¹ This enables a manufacturer of a supplement containing a new dietary ingredient to skip the notification provision and instead seek, as one scholar terms it, “an optional

¹⁷⁷ *Id.* § 4 (codified at 21 U. S. C. § 342(f)).

¹⁷⁸ *Id.* § 8 (codified at 21 U. S. C. § 350b(a)(1)). A new use of an existing dietary supplement or an increase in the recommended dose does not make the dietary supplement new. CDSL Report, *supra* note 73, at 20.

¹⁸⁰ Pub. L. No. 103-417, § 8 (codified at 21 U. S. C. § 350b(b)).

¹⁸¹ *Id.* Additionally, the ruling of the Secretary on the petition is considered final agency action. *Id.*

approval scheme.”¹⁸² Seeking (and receiving) this optional approval rather than issuing a notification would likely eliminate the possibility of FDA action against the new dietary ingredient once marketing began.

As a note, the DSHEA provisions regarding the safety of new dietary ingredients are linked to the DSHEA provisions of safety for all dietary supplements. Thus, like with dietary supplements in general,¹⁸³ with new dietary ingredients, the FDA bears the burden in proving adulteration.

Additionally, the DSHEA made it a prohibited act to introduce or deliver for introduction into interstate commerce a dietary supplement that is unsafe under the new dietary ingredient provisions of the DSHEA.¹⁸⁴ The enforcement of this new provision could be problematic because the DSHEA provisions on new dietary ingredients do not refer to unsafe dietary supplements.¹⁸⁵

7. Dietary Supplement Good Manufacturing Practices

The DSHEA granted the Secretary the ability to issue regulations covering good manufacturing practices (“GMPs”) for dietary supplements.¹⁸⁶ Such regulations may cover preparation, packaging and handling of dietary supplements and may include expiration date labeling.¹⁸⁷ Such regulations must “be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology.”¹⁸⁸

¹⁸²BASS, *supra* note 71, at 41. Such a provision was added to appease sectors of the dietary supplement industry craving “greater certainty regarding new dietary ingredients.” *Id.*

¹⁸³Pub. L. No. 103-417, § 4 (codified at 21 U. S. C. § 342(f)(1)). For a more detailed discussion on the interaction of the general DSHEA safety provisions for dietary supplements and those for new dietary ingredients, *see* BASS, *supra* note 71, at 41-42.

¹⁸⁴Pub. L. No. 103-417, § 10 (codified at 21 U. S. C. § 331(v)).

¹⁸⁵BASS, *supra* note 71, at 42.

¹⁸⁶Pub. L. No. 103-417, § 9 (codified at 21 U. S. C. § 342(g)).

¹⁸⁷*Id.* (codified at 21 U. S. C. § 342(g)(1)).

¹⁸⁸*Id.* (codified at 21 U. S. C. § 342(g)(2)). Further, the Secretary must follow notice and comment rulemaking for such

8. Miscellaneous Provisions

Finally, the DSHEA enacted several other provisions. First, the DSHEA rescinded the advance notice of proposed rulemaking concerning dietary supplements issued by the FDA in June of 1993 to comply with the DSA.¹⁸⁹ This avoided overlap problems between the DSA and DSHEA. Second, the DSHEA created the Commission on Dietary Supplement Labels (“CDSL”).¹⁹⁰ The CDSL was to be an independent executive branch agency with seven members appointed by the President.¹⁹¹ The purpose of the CDSL was to issue recommendations regarding “the regulation of label claims and statements for dietary supplements, including the use of literature in connection with the sale of dietary supplements and procedures for the evaluation of such claims.”¹⁹² Finally, the DSHEA created the Office of Dietary Supplements (“ODS”) to be placed within the National Institutes of Health.¹⁹³ The purpose of the ODS was to conduct, coordinate, and assemble research regarding dietary supplements and to serve as the principal dietary supplement advisor to the Secretary.¹⁹⁴

C. FDA Activity Regarding Dietary Supplements Post-DSHEA

While the DSHEA enacted a significant and detailed new framework for dietary supplements, the DSHEA left it to the Secretary, through the FDA, to implement and flesh out this new framework.¹⁹⁵ The sections

regulations. *Id.*

¹⁸⁹*Id.* § 11. The specific rulemaking rescinded appeared in 58 Fed. Reg. 33,690 (June 18, 1993). The FDA rescinded this rulemaking in 59 Fed. Reg. 62,644 (Dec. 6, 1994).

¹⁹⁰Pub. L. No. 103-417, § 12.

¹⁹¹*Id.*

¹⁹²*Id.* Such recommendations were to be made in final report from within two years from enactment of the DSHEA. *Id.* Further, the FDA was to act on such recommendations within ninety days of issuance of the final report and complete rulemaking within two years of issuance of the final report. *Id.*

¹⁹³*Id.* § 13.

¹⁹⁴*Id.*

¹⁹⁵This was made all the more important by the fact that little legislative history was adopted as part of the DSHEA. Specifically, the Statement of Agreement passed by the House and the Senate read: “This statement comprises the entire legislative history for the Dietary Supplement Health and Education Act of 1994, S.784. It is the intent of the chief sponsors

below explore notable details, successes, and failures of the FDA's implementation of the DSHEA.

1. Dietary Supplement Labeling and Labeling Exemptions

The DSHEA enacted several new provisions concerning dietary supplement labeling,¹⁹⁶ but it left most of the work to be done by FDA implementation. Specifically, the CDSL was to first issue a final report on dietary supplement labeling on which the FDA was then to act.¹⁹⁷ The CDSL issued its final report on November 27, 1997.¹⁹⁸ The CDSL final report covered recommendations on safety, label statements, health claims, substantiation of claims, and botanical supplements.¹⁹⁹ As to the labeling exemptions under the DSHEA, the CDSL final report offered guidance that the FDA undertake “proactive monitoring of practice in this area... as resources permit and that regulatory guidance be developed if necessary.”²⁰⁰ The CDSL final report specified that providing balanced, truthful information to consumers was the primary goal and as such the exemption should be used with care and its requirement be strictly observed.²⁰¹ As to specific labeling, the CDSL simply stated that “[t]he Commission supports the informative label format mandated by DSHEA and urges orderly implementation of appropriate regulations.”²⁰²

of the bill . . . that no other reports or statements be considered as legislative history for the bill.” 140 CONG. REC. H11179 (daily ed. Oct. 6, 1999). The Statement of Agreement went on to list only five short, limited points to include in the legislative history. *Id.*

¹⁹⁶Pub. L. No. 103-417, §§ 3 (codified at 21 U. S. C. § 343-2), 7 (codified at 21 U. S. C. §§ 343(s), 343(q)(5)(F), 343(r)(2)(F), 350(b)(2)); 10 (codified at 21 U. S. C. § 343(s)), 12. *See* discussion *supra* Part.III.B.

¹⁹⁷Pub. L. No. 103-417, § 12.

¹⁹⁸CDSL Report, *supra* note 73.

¹⁹⁹*Id.*

²⁰⁰*Id.* at xi.

²⁰¹*Id.* at 47. For recent FDA activity regarding such third party labeling and food products including dietary supplements, *see* Letter from Margaret M. Dotzel, Associate Commission for Policy, Center for Food Safety and Applied Nutrition, Food and Drug Administration, to Daniel J. Popeo

& Paul D. Kamenar, Washington Legal Foundation (Nov. 1, 2001), *available at* <http://www.cfsan.fda.gov/~dms/labwww.html>.

²⁰²CDSL Report, *supra* note 73, at 29. This response was partly shaped by the fact that at the time of issuance of the CDSL final report the FDA had already issued proposed and then final regulations for dietary supplement labeling regarding identity, nutrition, and ingredient labeling. *See* 60 Fed. Reg. 67,194-67,224 (Dec. 28, 1995); 62 Fed. Reg. 49,859-49,868 (Sep. 23, 1997).

The FDA did not wait for the CDSL final report before issuing detailed dietary supplement labeling regulations under the DSHEA. In 1995, the FDA issued proposed rules regarding the statement of identity on dietary supplement labels, specific nutrition and ingredient labeling for dietary supplements, and type-size requirements for such labels.²⁰³ These regulations were issued in final form in 1997,²⁰⁴ and they became effective March 23, 1999.²⁰⁵ The regulations require that the statement of identity on a dietary supplement product label must contain the term dietary supplement.²⁰⁶ This could be modified by dropping the term “dietary” and substituting the name of the dietary supplement ingredient (such as “Vitamin C Supplement”) or including other descriptive terms (such as “Herbal Supplement”).²⁰⁷ However, generic terms (such as “Food Supplement”) are not allowed because such terms failed to identify or describe the dietary ingredient or ingredients present in the supplement.²⁰⁸

The labeling regulations for dietary supplement go into much more detail (greater than can be presented here), but a cursory glance at some of the more prominent provisions is warranted. The regulations require that dietary supplements list the serving size, particularly by actually using the term “serving size” instead of an alternative term like “recommended use” or “dose.”²⁰⁹ Also required is that all dietary supplement labels list the fourteen nutrients mandatory for conventional food labels unless such nutrients are absent or present in an insignificant amount.²¹⁰ Further, for dietary supplements containing dietary ingredients that

²⁰³60 Fed. Reg. 67,194 (Dec. 28, 1995).

²⁰⁴62 Fed. Reg. 49,826 (Sep. 23, 1997) (codified in scattered sections of 21 C. F. R.).

²⁰⁵*Id.*

²⁰⁶*Id.* at 49,847 (codified at 21 C. F. R. § 101.3(g)).

²⁰⁷*Id.* at 49,827 (codified at 21 C. F. R. § 101.3(g)).

²⁰⁸*Id.* The regulations also stipulated that type-size requirements in effect for conventional foods would not be altered for dietary supplements. *Id.* Thus the statement of identity for dietary supplements was required to “be in a size reasonably related to the most prominent printed matter” on the label. *Id.* (codified at 21 C. F. R. § 101.3(d)).

²⁰⁹*Id.* at 49,849. (codified at 21 C. F. R. § 101.36).

²¹⁰*See id.* (codified at 21 C. F. R. § 101.36). The fourteen nutrients mandatory for conventional food labels are calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrates, dietary fiber, sugars, protein, vitamin A,

do not have an RDI or DRV, dietary supplement labels must bear a footnote stating as such,²¹¹ and the label must list all such dietary ingredients under a heavy bar and after all listed dietary ingredient with an RDI or DRV.²¹² The regulations also took the important step of requiring dietary supplement labels to include nutrition informational in a box entitled “Supplement Facts” rather than the title “Nutrition Facts” used on conventional foods.²¹³ This serves to easily distinguish dietary supplements from conventional foods, especially when dietary supplements are sold in conventional food form.

The FDA also promulgated an additional set of final rules in 1997 that addressed certain labeling issues.²¹⁴ This regulation allows a dietary supplement containing a dietary ingredient for which there is no RDI or DRV to state the percentage level of such dietary ingredient without the need for approval from the FDA.²¹⁵ This is something that is not allowed on conventional food because conventional food is forbidden to list non-RDI or DRV nutrients on the nutrition label.

While the above 1997 final rules took care of much of the details of the design and content of dietary supplement labels, the FDA proposed additional labeling rules in 1999.²¹⁶ These proposed rules stated that dietary supplements could, in addition to listing nutritional information on a per serving basis, also list such

vitamin C, calcium, and iron. 21 C. F. R. § 101.9(c). The regulations also refuse to exempt herbal and botanical dietary supplements from listing these fourteen nutrients if present in a significant amount. 62 Fed. Reg. 49,828 (Sep. 23, 1997).

²¹¹62 Fed. Reg. 49,826, 49,832, 49,850 (Sep. 23, 1997) (codified at 21 C. F. R. § 101.36(b)(2)(iii)(F)).

²¹²*Id.* at 49,838, 49,851-852 (codified at 21 C. F. R. § 101.36(e)(6)(ii)).

²¹³*Id.* at 49,851 (codified at 21 C. F. R. § 101.36(e)(1)). Some comments to this proposed rule argued that the title “Nutrition Facts” should be allowed for dietary supplement because the DSHEA used the term nutritional information for dietary supplement labels, that the information provided on the dietary supplement label was at least in part nutritional information, and that dietary supplements were marketed for their nutritional value. *Id.* at 49,837. The FDA rejected these arguments in favor of facilitating consumer identification of dietary supplements versus conventional food. *Id.*

²¹⁴62 Fed. Reg. 49,859 (Sep. 23, 1997) (codified in scattered sections of 21 C. F. R.).

²¹⁵*Id.* at 49,867 (codified at 21 C. F. R. § 101.13(q)(3)(ii)). The label must also list the actual amount of the dietary supplement per serving next to the percentage level claim. *Id.* (codified at 21 U. S. C. § 101.13(q)(3)(ii)(A)).

²¹⁶64 Fed. Reg. 1765 (Jan. 12, 1999).

nutritional information on a per day basis.²¹⁷ Further, if the dietary supplement is recommended to be taken more than once a day, the total qualitative amount and the percent of daily value of each dietary ingredient recommended to be taken per day must appear on the label.²¹⁸ As of April 2004 the FDA has not issued a final rule on this point.

2. New Dietary Ingredients

As a tradeoff for relaxing the adulteration regulations for dietary supplements and removing dietary supplements from food additive and GRAS procedures, the DSHEA enacted special safety provisions for new dietary ingredients.²¹⁹ Included within these new safety procedures was a provision requiring the Secretary to be notified prior to the introduction of a dietary supplement containing a new dietary ingredient.²²⁰

In 1996, the FDA issued proposed rules establishing a premarket notification procedure for new dietary ingredients.²²¹ And in 1997 the FDA issued final rules regarding new dietary ingredient premarket notification.²²² These regulations apply only to a new dietary ingredient “that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered.”²²³ The notification is to include: (1) the complete address of the manufacturer or distributor, (2) the name of the dietary supplement, (3) a description of the dietary supplement including the level at which the new dietary

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ Pub. L. No. 103-417, § 8 (codified at 21 U. S. C. § 350b). *See* discussion *supra* Part III.B.6.

²²⁰ *Id.* Specifically, a dietary supplement can avoid being deemed adulterated if

[t]here is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

Pub. L. No. 103-417, § 8 (codified at 21 U. S. C. § 350b(a)(2)).

²²¹ 61 Fed. Reg. 50,774 (Sep. 27, 1996).

²²² 62 Fed. Reg. 49,886 (Sep. 23, 1997) (codified at 21 C. F. R. § 190.6).

²²³ *Id.* at 49,892 (codified at 21 C. F. R. § 190.6(a)). Premarket notification of new dietary ingredients thus applies only to new dietary ingredients described in section 413(a)(2) of the DSHEA. *See* Pub. L. No. 103-417, § 8 (codified at 350b(a)(1)).

ingredient is present in the new dietary supplement, and (4) the conditions of recommend or suggested use.²²⁴ Further, the notification must include the history of use or other evidence demonstrating that the dietary supplement will reasonably be expected to be safe for its intended use.²²⁵ The regulations also prohibit introduction of a new dietary ingredient within seventy-five days of filing of the premarket notification.²²⁶ Finally, the regulations provide that a failure of the FDA to respond to the notification, while not barring introduction of the dietary supplement, does not constitute approval by the FDA.²²⁷ This reinforces the point that the DSHEA merely created a premarket notification procedure for new dietary supplements and not a premarket approval procedure as with drugs.

3. Nutrient Content Claims

A nutrient content claim is one that describes the level of a nutrient in a conventional food or dietary supplement by using certain terms or compares the level of nutrients in such product to another product.²²⁸ The NLEA allowed nutrient content claims to be made for both conventional food and dietary supplements if the FDA first promulgated a regulation regarding such a claim.²²⁹ The DSHEA did not change this regulatory framework. The first FDA action post-DSHEA concerning nutrient content claims for dietary

²²⁴62 Fed. Reg. 49,886, 49,892 (Sep. 23, 1997) (codified at 21 C. F. R. § 190.6(b)). If there is no recommend or suggested conditions of use, the notification must include the ordinary conditions of use for the dietary supplement. *Id.*

²²⁵*Id.* Further the notification must include a signature. *Id.*

²²⁶*Id.* (codified at 21 C. F. R. § 190.6(c)). The regulations also provide for supplemental information concerning history of use and safety to be submitted after the initial notification and that the FDA will not disclose the notification submission for ninety days. *Id.* (codified at 21 C. F. R. § 190.6(d)-(e)).

²²⁷*Id.* (codified at 21 C. F. R. § 190.6(f)). As of September 10, 2001 the FDA had received and acted on over ninety-six notifications. OFFICE OF NUTRITIONAL PRODUCTS, LABELING AND DIETARY SUPPLEMENTS, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, NEW DIETARY INGREDIENTS IN DIETARY SUPPLEMENTS (Sep. 10, 2001), at <http://www.cfsan.fda.gov/~dms/ds-ingrd.html>. Most notifications were filed without comment by the FDA. *Id.*

²²⁸OFFICE OF NUTRITIONAL PRODUCTS, LABELING, AND DIETARY SUPPLEMENTS, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, CLAIMS THAT CAN BE MADE FOR CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS (Sep. 2003), available at <http://www.cfsan.fda.gov/~dms/hclaims.html> [hereinafter CLAIMS].

²²⁹Pub. L. No. 101-535, 104, Stat. 2352 (1990) (codified as amended at 21 U. S. C. § 343(r)). Generally the NLEA regulation process begins with a petition from a manufacturer. 21 C. F. R. § 101.69.

supplements came in 1995. In that year, the FDA published proposed rules for certain nutrient content claims for both conventional food and dietary supplements.²³⁰ Then in 1997, the FDA promulgated final version of these rules.²³¹ These final rules specify several terms that can be used to describe the nutrient content in dietary supplements. First, while dietary supplements can list nutrition information for nutrients that have no RDI and DRV, the regulations make clear “that the use of defined nutrient content claims, such as ‘more’ and ‘high,’ remains limited, for both conventional foods and dietary supplements, to those dietary ingredients that have RDI’s or DRV’s.”²³² Second, the regulations allow the following nutrient content terms to be used on dietary supplement labels: (1) “high,” “rich in,” or “excellent source,”²³³ (2) “good source,” “contains,” or “provides,”²³⁴ (3) “more,” “fortified,” “enriched,” or “added.”²³⁵ Third, a separate set of regulations issued the same day allow dietary supplements to use the terms “high potency,” and “antioxidant.”²³⁶ Finally, the FDA currently has issued proposed rules to amend sodium level regulations in conventional foods and dietary supplements that use the term “healthy.”²³⁷

When the FDCA was amended by the Food and Drug Administration Modernization Act of 1997 (“FDAMA”), it allowed nutrient content claims for conventional food and dietary supplements to be made by an additional route.²³⁸ Specifically, the FDAMA allowed nutrient content claims to be made without the need for an FDA

²³⁰60 Fed. Reg. 67,176 (Dec. 28, 1995).

²³¹62 Fed. Reg. 49,859 (Sep. 23, 1997) (codified in scattered sections of 21 C. F. R.); 62 Fed. Reg. 49,868 (Sep. 23, 1997) (codified at 21 C. F. R. §§ 101.54, 101.50).

²³²62 Fed. Reg. 49,859, 49,861 (Sep. 23, 1997). However, percentage nutrient content claims for dietary ingredients with no RDI or DRV are allowed. See discussion *supra* Part III.C.1.

²³³62 Fed. Reg. 49,859, 49,867 (codified at 21 C. F. R. § 101.54(b)). To use these terms, the dietary supplement must have “20 percent or more of the RDI or the DRV per reference amount customarily consumed.” *Id.*

²³⁴*Id.* (codified at 21 C. F. R. § 101.54(c)). To use these terms, the dietary supplement must have “10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.” *Id.*

²³⁵*Id.* (codified at 21 C. F. R. § 101.54).

²³⁶62 Fed. Reg. 49,868, 49,880 (Sep. 23, 1997) (codified at 21 C. F. R. § 101.54(e)). For a list of more approved nutrient content terms, see 21 C. F. R. §§ 101.13, 101.54, 101.56, 101.60-101.62; CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, A FOOD LABELING GUIDE, Appendix A (June 1999), available at <http://www.cfsan.fda.gov/~dms/flg-6a.html>; CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, A FOOD LABELING GUIDE, Appendix B (June 1999), available at <http://www.cfsan.fda.gov/~dms/flg-6b.html>.

²³⁷68 Fed. Reg. 8163 (Feb. 20, 2003).

²³⁸Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified in scattered sections of 21 U. S. C.); see OFFICE OF LABELING, FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: NOTIFICATION OF A HEALTH CLAIM OR NUTRI-

regulation if based upon current, published authoritative statements from certain scientific bodies.²³⁹ The FDAMA specified premarket notification procedures that must be met in such a case.²⁴⁰ If these notification procedures are met and the FDA does not act within the specified statutory time frame, the nutrient content claim may be made. The FDA lists only one dietary supplement nutrient content claim made under this provision – a 2001 petition concerning dietary supplements containing chlorine.²⁴¹

4. Structure/Function Claims

Under the DSHEA, a claim is a structure/function claim if

the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in

ENT CONTENT CLAIM BASED ON AN AUTHORITATIVE STATEMENT OF A SCIENTIFIC BODY (June 11, 1998), *available at* <http://www.cfsan.fda.gov/~dms/hclmguid.html> [hereinafter Guidance Doc.].

²³⁹Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified at 21 U. S. C. § 343(r)).

²⁴⁰*Id.* (codified at 21 U. S. C. § 343(r)(2)(G)). Specifically, a nutrient content claim may be made without an FDA regulation covering such claim if

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;

(ii) a person has submitted to the Secretary, at least 120 days... before the first introduction into interstate commerce of the food with a label containing the claim,

(I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied,

(II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and

(III) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with [existing regulations and statutory sections concerning labeling terms, nutrient content claims, and false and misleading claims]... and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

21 U. S. C. § 343(r)(2)(G).

²⁴¹CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION. NUTRIENT CONTENT CLAIMS NOTIFICATION FOR CHLORINE CONTAINING FOODS (Aug. 20, 3001), *available at* <http://www.cfsan.fda.gov/~dms/flcholin.html>. The FDA did not choose to act within the 120 day statutory period and thus the claim was allowed to be used. *Id.*

humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient.²⁴²

The FDA allows structure/function claims to be made for conventional foods without notification so long as such statements are truthful, not misleading, and derive from the nutritive value of the food.²⁴³ Further such structure/function claims for conventional foods must concern “a non-disease-related effect on the structure or function of the body and the claimed effect derived from a food attribute.”²⁴⁴ The DSHEA preserved this framework but enlarged the scope of structure/function claims that could be made for dietary supplements without being considered drug claims.²⁴⁵ In 1995, the FDA issued proposed regulations concerning structure/function claims for dietary supplements.²⁴⁶ The FDA issued these regulations in final form in 1997.²⁴⁷ Specifically, these regulations spell out the exact language of the disclaimer or disclaimers that must appear on the dietary supplement label if a structure/function claim is made and the placement and size of the disclaimer on the label.²⁴⁸

In 1996, the FDA issued proposed rules for the notification and substantiation procedure under the DSHEA for dietary supplements making structure/function claims.²⁴⁹ The FDA issued its final rule pertaining to notification and substantiation in 1997.²⁵⁰ This rule provides that notification must be made within thirty

²⁴³21 U. S. C. §§ 321(n), 343(a)(1); 62 Fed. Reg. 49,859, 49,860 (Sep. 23, 1997); CLAIMS, *supra* note 228.

²⁴⁴65 Fed. Reg. 999, 1001 (Jan. 6, 2000).

²⁴⁵Pub. L. No. 103-417, § 6 (codified at 21 U. S. C. § 343(r)(6)); *see* discussion *supra* Part III.B.4. To make such claims, the manufacturer of the dietary supplement must have substantiation of the claims, must include a disclaimer on the label that such claims have not been evaluated by the FDA and are not intended to treat a disease, and must notify the FDA of the claim within thirty days of introducing the product. Pub. L. No. 103-417, § 6 (codified at 21 U. S. C. § 343(r)(6)).

²⁴⁶60 Fed. Reg. 67,176 (Dec. 28, 1995).

²⁴⁷62 Fed. Reg. 49,859 (Sep. 23, 1997) (codified in scattered sections of 21 C. F. R.). The regulations make clear that a dietary supplement may follow the previous structure/function framework for conventional foods if it qualifies for the food exemption under 21 U. S. C. § 321(g)(1)(C) unless the dietary supplement contains no nutritive value (in which case it must comply with the DSHEA procedures). *Id.* at 49,863-864.

²⁴⁸*Id.* at 49,867-868 (codified at 21 C. F. R. §101.93).

²⁴⁹61 Fed. Reg. 50,771 (Sep. 27, 1996).

²⁵⁰62 Fed. Reg. 49,883 (Sep. 23, 1997) (codified at 21 C. F. R. § 101.93).

days of introducing the dietary supplement with the structure/function claim.²⁵¹ Further, the notification must include: (1) the name and address of the manufacturer or distributor, (2) the text of the claim made, (3) the name of the dietary ingredient that is the subject of the claim, (4) the name of the dietary supplement, including the brand name, on which the claim appears, and (5) a signature certifying that the manufacturer or distributor has substantiation that the claims is truthful and not misleading.²⁵²

In 1998, the FDA undertook the more monumental tasks of (1) defining the general types of structure/function claims that could be made on dietary supplement labels and (2) attempting to distinguish such claims from disease or health-related condition claims – claims “that describe the relationship between a nutrient and a disease or health related condition.”²⁵³ The FDA issued final rules on this topic in 2000 after receiving over 235,000 comments and holding a public meeting.²⁵⁴ The final rule distinguishes general structure/function claims (which need no FDA prior approval) from disease or health-related condition claims (which need FDA authorization, or premarket notification under the FDAMA, or else are handled as new drug claims).²⁵⁵ The final rule promulgated three main provisions.²⁵⁶ First, the FDA preserved the definition of “disease or health-related condition” in conjunction with claims made by dietary supplements.²⁵⁷ Second, the regulations narrowed what is considered a disease of health-related condition for dietary supplement purposes:

²⁵¹ *Id.* at 49,886.

²⁵² *Id.*

²⁵³ 63 Fed. Reg. 23,624 (April 29, 1998).

²⁵⁴ 65 Fed. Reg. 1000 (Jan. 6, 2000) (codified at 21 U. S. C. § 101.93)

²⁵⁵ *Id.* at 1001, 1050. The FDA noted that while it “believes that dietary supplements have potential benefits for consumers, dietary supplements labeled with unproven disease claims, i.e., those that have not met the requirements of health claim authorization or new drug approval, can pose serious risks.” *Id.* For more on health claims, *see* discussion *infra* Part III.C.5.

²⁵⁶ 65 Fed. Reg. 1000, 1050 (Jan. 6, 2000) (codified at 21 C. F. R. § 101.93).

²⁵⁷ *Id.* at 1000. The definition states

[d]isease or health-related condition means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.

21 C. F. R. § 101.14(a)(5). The regulations codified this definition for dietary supplement purposes at 21 C. F. R. § 101.93(g).

menopause, aging, and pregnancy are not themselves diseases but... certain conditions associated with them are diseases if they are recognizable to consumers or health professionals as abnormal [and]... [c]ommon conditions associated with natural states or processes that do not cause significant or permanent harm will not be treated as diseases.²⁵⁸

Thus conditions like hot flashes, hair loss due to aging, and certain types of acne are not considered diseases and thus are eligible for dietary supplement structure/function claims.²⁵⁹ Finally, the final rule allows dietary supplement manufacturers to substantiate label claims by citing (on the label) to the title of publication referring to a disease so long as, in the context of the whole label, such citation does not imply “that the product may be used to diagnose, treat, mitigate, cure, or prevent disease.”²⁶⁰

5. Health Claims

While the DSHEA did expand the types of statements of nutritional support that could be made on dietary supplement labels without prior approval by the FDA,²⁶¹ it did not include any provisions for health-related condition or disease claims (“health claims”) for dietary supplements. This was left to other statutes and regulations. Health claims are claims that “describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition.”²⁶²

(i) The NLEA

²⁵⁹*Id.* at 1000, 1050 (codified at 21 C. F. R. § 101.93(g)).

²⁶⁰*Id.* For a summary of structure/function regulations see CENTER FOR FOOD SCIENCE AND APPLIED NUTRITION, SMALL ENTITY COMPLIANCE GUIDE: STRUCTURE/FUNCTION CLAIMS, (Jan. 9, 2002), available at <http://www.cfsan.fda.gov/~dms/sclmguid.html>.

²⁶¹See discussion *supra* Parts III.B.4, III.C.4.

²⁶²CLAIMS, *supra* note 228; see also 21 C. F. R. § 101.14.

One way that a health claim may appear on a dietary supplement is by following provisions under the NLEA allowing for health claims upon approval by the FDA after careful review of scientific evidence.²⁶³

The DSHEA did not alter the NLEA framework regarding health claims for dietary supplements. In 1994, before passage of the DSHEA, the FDA had issued final rules on health claims for dietary supplements.²⁶⁴ These regulations stated that dietary supplements would be held to the same health claim standards as conventional foods.²⁶⁵ Rather than enact new health claim provisions for dietary supplements, the DSHEA appointed the CDSL to issue recommendations on such health claims.²⁶⁶ The FDA was then to timely complete final rulemaking on the CDSL recommendations or else the 1994 FDA final regulations on dietary supplement health claims would be rescinded.²⁶⁷ The CDSL issued its final report in 1999, specifically recommending that “[t]he process for approval of health claims as defined by the NLEA should remain the same for dietary supplements and conventional food.”²⁶⁸ This effectively preserved the FDA’s 1994 final regulations on health claims and dietary supplements. Thus a dietary supplement may make a health claim by complying with the NLEA provisions regarding health claims for conventional foods.

Under the NLEA, a health claim may be made if the FDA has issued a regulation permitting such a health claim.²⁶⁹ Such regulation shall issue

²⁶³Pub. L. No. 101-535, 104, Stat. 2352 (1990) (codified as amended at 21 U. S. C. § 343(r)).

²⁶⁴59 Fed. Reg. 395 (Jan. 4, 1994).

²⁶⁵*Id.* The NLEA had specifically exempted dietary supplements from these new health claim provisions for conventional foods, instead leaving it to the Secretary to promulgate regulations. Pub. L. No. 101-535, 104 Stat. 2352 (1990) (codified at 21 U. S. C. § 343(r)(5)(D)).

²⁶⁶Pub. L. No. 103-417, §12, 108 Stat. 4332 (1994).

²⁶⁷*Id.*

²⁶⁸CDSL Report, *supra* note 73, at 35.

²⁶⁹Pub. L. No. 101-535, 104, Stat. 2352 (1990) (codified as amended at 21 U. S. C. § 343(r)(3)(A)(i)). The Secretary may issue such a regulation

only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.²⁷⁰

The key phrase in this statutory language is “significant scientific agreement.” To help manufacturers of dietary supplements (as well as conventional foods) determine what the FDA considers to be “significant scientific agreement,” in 1999 the FDA issued a guidance document.²⁷¹ The guidance documents states that the “FDA’s determination on significant scientific agreement represents the agency’s best judgment as to whether qualified experts would likely agree that the scientific evidence supports the substance/disease relationship that is the subject of a proposed health claim.”²⁷²

This is as strict yet objective standard designed to make “the key determination of whether a change in the dietary intake of the substance will result in a change in a disease endpoint.”²⁷³

Under the NLEA and accompanying regulations, several health claims have been approved for use on dietary supplement (as well as conventional food) labels.²⁷⁴ These range from calcium-osteoporosis claims to folate-neural tube defects claims to plant stanols-coronary heart disease claims.²⁷⁵

if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet.

Id. (codified as amended at 21 U. S. C. § 343(r)(3)(A)(ii)). Generally the regulation process begins with a petition by a manufacturer. 21 C. F. R. §§ 101.70.

²⁷¹CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY – SIGNIFICANT SCIENTIFIC AGREEMENT IN THE REVIEW OF HEALTH CLAIMS FOR CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS (Dec. 22, 1999), available at <http://www.cfsan.fda.gov/~dms/ssaguide.html>.

²⁷²*Id.*

²⁷³*Id.*

²⁷⁴21 C. F. R. §§ 101.72-101.83; CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, A FOOD LABELING GUIDE, Appendix C (Nov. 2000), available at <http://www.cfsan.fda.gov/~dms/flg-6c.html> [hereinafter Food Label Appendix C]; see *Approved Health Claims*, FOOD TECHNOLOGY, Dec. 2003, at 88-89.

²⁷⁵21 C. F. R. §§ 101.72-101.83; Food Label Appendix C, *supra* note 274; see *Approved Health Claims*, *supra* note 274.

(ii) *The FDAMA and Health Claims Based on Authoritative Statements*

The FDAMA provided an additional means for listing health claims on the labels of conventional foods: use of a premarket notification system for health claims based on an authoritative statement from certain scientific bodies.²⁷⁶ Thus health claims may be made under the FDAMA without the need for premarket approval by the FDA. However, the FDAMA did not enact this premarket notification system for health claims on dietary supplement labels.²⁷⁷

Noting that the FDAMA had created an additional health claim procedure for conventional foods but not for dietary supplement, the FDA issued proposed rules in 1999 to equalize the health claim treatment of dietary supplements and conventional foods.²⁷⁸ The FDA stated that it “believes that, for health claims, conventional foods and dietary supplements should be subject to the same standards and procedures, including the notification procedure provided by FDAMA.”²⁷⁹ As of April 2004, the FDA has yet to issue final rules on this subject.²⁸⁰

(iii) *Qualified Health Claims*

²⁷⁶Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified at 21 U. S. C. § 343(r)(3)). The FDAMA enacted the same premarket notification scheme for nutrient content claims based on authoritative statements. For a listing of these pre-notification procedures see discussion *supra* Part III.C.3, especially note 240.

²⁷⁷See Pub. L. No. 105-115, 111 Stat. 2296 (1997) (codified at 21 U. S. C. § 343(r)(3)). The FDAMA is limited to conventional foods only here.

²⁷⁸64 Fed. Reg. 3250 (Jan. 21, 1999).

²⁷⁹*Id.* at 3251.

²⁸⁰The proposed rules do, however, point to a guidance document. *Id.* at 3252; see Guidance Doc., *supra* note 238. Additionally, currently three health claims based on authoritative statements are in use for conventional foods (but not dietary supplements). See Food Label Appendix C, *supra* note 274; CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, HEALTH CLAIM NOTIFICATION FOR WHOLE GRAIN FOODS WITH MODERATE FAT CONTENT (Dec. 9, 2000), available at <http://www.cfsan.fda.gov/~dms/flgrain2.html>; see also *Approved Health Claims*, *supra* note 274.

In 1999, a U.S. Court of Appeals ruled that under the commercial speech doctrine of the First Amendment, the FDA could not reject health claims for dietary supplements based on their potential to mislead unless the FDA found that no disclaimer would eliminate such potential deception.²⁸¹ Thus, the opinion meant that the FDA could not insist on the significant scientific standard under the NLEA as the sole means for approving health claims in dietary supplement. Such health claims that do not meet the NLEA significant scientific standard are referred to by the FDA as qualified health claims.²⁸²

In response to the court decision, the FDA issued a notice in 2000 delineating circumstances in which the agency might exercise enforcement discretion for a qualified health claim in dietary supplement labeling.²⁸³ This notice was followed by a FDA notice in 2002 of forthcoming interim industry guidance for making qualified health claims for dietary supplements.²⁸⁴ This notice further specified that these interim procedures would also be applied to qualified health claims for conventional foods.²⁸⁵ In December of 2002, the FDA also instituted “the Consumer Health Information for Better Nutrition Initiative, to make available more and better information about conventional human food and human dietary supplements.”²⁸⁶ This initiative resulted in the issuance in 2003 of the promised interim procedures for health claims in dietary supplements and conventional foods.²⁸⁷ As of April 2004, these procedures are currently in effect on an interim basis.

²⁸¹Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999). The court went on to invalidate the FDA’s decision not to authorize, under the NLEA, health claims for dietary fiber and cancer, antioxidant vitamins and cancer, omega-3 fatty acids and coronary heart disease, and folate neural tube defects. *Id.* The FDA subsequently revoked its decision not to authorize such health claims. 65 Fed. Reg. 58,917 (Oct. 3, 2000). In 2000 and 2001, the FDA announced its decision on these health claims in several letters and Talk Papers. *See* <http://www.cfsan.fda.gov/~dms/ds-labl.html#qualified> for a specific list of letters and Talk Papers (last visited April 26, 2004).

²⁸²68 Fed. Reg. 66,040, 66,041 (Nov. 25, 2003).

²⁸³65 Fed. Reg. 59,855 (Oct. 6, 2000).

²⁸⁴67 Fed. Reg. 78,002 (Dec. 20, 2002).

²⁸⁵*Id.* at 78,003.

²⁸⁶68 Fed. Reg. 41,387 (July 11, 2003).

²⁸⁷*Id.* CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, INTERIM PROCEDURES FOR

The interim procedures provide that the FDA will regulate qualified health claims for dietary supplements and conventional foods “based on the extent to which the totality of the publicly available evidence supports the claim [and]... [d]ifferent levels of evidence will result in different qualifying language.”²⁸⁸ The interim procedures outline the general process for petitioning the FDA for a qualified health claim,²⁸⁹ and they create an evidence-based ranking system to “rate the strength of the evidence behind a proposed substance/disease relationship.”²⁹⁰ The result of the evidence-based ranking system is placement of the qualified health claim in one of three categories: (1) a moderate or good level of comfort that the claimed relationship is scientifically valid,²⁹¹ (2) a low level of comfort that the claimed relationship is scientifically valid,²⁹² or (3) an extremely low level of comfort that the claimed relationship is scientifically valid.²⁹³

QUALIFIED HEALTH CLAIMS IN THE LABELING OF CONVENTIONAL HUMAN FOOD AND HUMAN DIETARY SUPPLEMENTS GUIDANCE (July, 2003), *available at* <http://www.cfsan.fda.gov/~dms/hclmgui3.html> [hereinafter INTERIM PROCEDURES]; CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, INTERIM EVIDENCE-BASED RANKING SYSTEM FOR SCIENTIFIC DATA GUIDANCE (July 2003), *available at* <http://www.cfsan.fda.gov/~dms/hclmgui4.html> [hereinafter INTERIM EVIDENCE]. Both of these guidance documents apply to qualified health claims for dietary supplements or conventional foods.

²⁸⁸INTERIM PROCEDURES, *supra* note 287.

²⁸⁹*Id.* The general petition procedure is as follows: (1) filing of the petition for review with a response from the FDA on completeness of the petition within 45 days; (2) prioritization by the FDA concerning review of the petition; (3) a sixty day public comment period; (4) scientific review by the FDA after the close of the comment period; (5) notification of a regulatory decision by the FDA within 270 days of receipt of the petition; (6) availability of reconsideration of the FDA’s decision. *Id.* Additionally, the substance of the petition is to comply with regulations for health claims under the significant scientific agreement standard of the NLEA; however, the petition need only demonstrate credible evidence supporting the claim. *Id.* For the NLEA regulations for health claims, *see* 21 C. F. R. § 101.70.

²⁹⁰INTERIM EVIDENCE, *supra* note 287. A simplified version of the evidence-based system is as follows: (1) define the relationship between the dietary supplement or conventional food at issue and the disease at issue; (2) collect and submit all relevant studies concerning the substance/disease relationship to be tested; (3) rate each study based on its experimental design; (4) rate each study for overall quality; (5) rate the strength of the total body of evidence based on quantity, consistency, and relevance to disease reduction; (6) rank the strength of the evidence for a health claim; (7) report the rank. *Id.*

²⁹¹*Id.* An example of a label statement in this category is “although there is scientific evidence supporting the claim, the evidence is not conclusive.” INTERIM PROCEDURES, *supra* note 287.

²⁹²INTERIM EVIDENCE, *supra* note 287. An example of a label statement in this category is “[s]ome scientific evidence suggests... however, FDA has determined that this evidence is limited and not conclusive.” INTERIM PROCEDURES, *supra* note 287.

²⁹³INTERIM EVIDENCE, *supra* note 287. An example of a label statement in this category is “[v]ery limited and preliminary scientific research suggests... FDA concludes that there is little scientific evidence supporting this claim.” INTERIM PROCEDURES, *supra* note 287.

Under the current interim procedures, the FDA issues letters in response to petitions for qualified health claims.²⁹⁴ As of April 2004, the FDA has received numerous petitions and has approved seven qualified health claims for dietary supplements.²⁹⁵

The FDA has issued an advance notice of proposed rulemaking (“ANPRM”) soliciting comments on permanent, long-term procedures for qualified health claims for dietary supplements and conventional foods.²⁹⁶ The ANPRM listed three options under consideration: (1) incorporate, through notice and comment rulemaking, the current interim standards and procedures, including the evidence-based ranking system, (2) change, through notice and comment rulemaking, the current significant scientific agreement standard for health claims under the NLEA to look at “the accuracy of the characterization of the evidence supporting the claim, instead of the underlying substance-disease relationship,” or (3) examine qualified health claims on a post-market basis wholly outside the NLEA health claims provisions.²⁹⁷ After an extension, the comment period for this ANPRM ended February 25, 2004.²⁹⁸ As of April 2004, a proposed rule had not yet issued.

6. Good Manufacturing Practices

The DSHEA did not enact good manufacturing practices (“GMPs”) for dietary supplement but rather subjected dietary supplements to GMPs for conventional food with the proviso that the Secretary could issue

²⁹⁴INTERIM PROCEDURES, *supra* note 287.

²⁹⁵CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, SUMMARY OF QUALIFIED HEALTH CLAIMS PERMITTED (Sep. 2003), *available at* <http://www.cfsan.fda.gov/~dms/qhc-sum.html>; *Qualified Health Claims*, FOOD TECHNOLOGY, Dec. 2003, at 90. Additionally, as of April 2004, eight petitions for qualified health claims are open for comment.

²⁹⁶68 Fed. Reg. 66,040 (Nov. 25, 2003).

²⁹⁷*Id.* at 66,042.

²⁹⁸69 Fed. Reg. 3868 (Jan. 27, 2004).

GMPs regulations specifically for dietary supplements.²⁹⁹ The FDA issued an ANPRM in 1997 inviting comments regarding the need for rulemaking for minimum GMPs for dietary supplements and dietary ingredients.³⁰⁰ Prior to the ANPRM, the FDA had received a draft proposal on dietary supplement GMPs from the dietary supplement industry.³⁰¹ In 2003, after a six year delay, the FDA finally issued proposed rules for dietary supplement GMPs.³⁰² The purpose of the proposed rules are “to the ensure that manufacturing practices will not result in an adulterated dietary supplement and that supplements are properly labeled.”³⁰³ The proposed rules focus on the personnel, equipment, production and process controls, holding and distributing, consumer GMPs complaints, and recordkeeping.³⁰⁴ After an extension, the comment period for the proposed rules ended August 11, 2003.³⁰⁵ As of April 2204, the FDA has yet to take any further action.

7. Specific Dietary Supplements

Since the DSHEA, the FDA has issued several regulations concerning specific groups of dietary supplements. In 1997, the FDA issued a final rule requiring label warnings on certain iron containing dietary supplements.³⁰⁶ The FDA issued this final rule to prevent accidental overdose of iron-containing dietary

²⁹⁹Pub. L. No. 103-417, § 9 (codified at 342(g)). GMPs for conventional foods are codified at 21 C. F. R. § 110.

³⁰⁰62 Fed. Reg. 5700 (Feb. 6, 1997).

³⁰¹*Id.* at 5700. In 1999, the CDSL had addressed dietary supplement GMPs in its final report. CDSL Report, *supra* note 73. The CDSL supported the effort of the FDA and industry to develop GMPs for dietary supplements. *Id.* at 21. The CDSL also stated the substantiation files for statements of nutritional support regarding dietary supplement should contain “[a]ssurance that GMPs were followed in the manufacture of product.” *Id.* at 44.

³⁰²68 Fed. Reg. 12,157 (March 13, 2003).

³⁰³*Id.* at 12,164 (March 13, 2003). The rules state that a “manufacturer of... a dietary supplement cannot make claims that state or imply that the... dietary supplement is safe and/or effective simply because it has been manufactured in compliance with current good manufacturing practice.” *Id.* However, a compliance statement might be lawful in context and with disclaimers. *Id.*

³⁰⁴*Id.* at 12,164-12,165, 12,175-12,218.

³⁰⁵68 Fed. Reg. 27,008 (May 19, 2003).

³⁰⁶62 Fed. Reg. 2217 (Jan. 15, 1997). Parts of this final rule were revoked in 2003 to comply with a U.S. Court of Appeals ruling. 68 Fed. Reg. 59,714 (Oct. 17, 2003); *see* CENTER FOR FOOD SCIENCE AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, IRON-CONTAINING SUPPLEMENTS AND DRUGS: LABEL WARNING STATEMENTS – SMALL ENTITY COMPLIANCE GUIDE (Oct. 17, 2003), *available at* <http://www.cfsan.fda.gov/~dms/secgiro2.html>.

supplements leading to poisoning and death in children under six years of age.³⁰⁷

The FDA recently issued a final rule deeming dietary supplements containing Ephedrine Alkaloids (popularly known as Ephedra) to be adulterated “because they present an unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or... under ordinary conditions of use.”³⁰⁸ This final rule utilized the DSHEA provisions for dietary supplement safety.³⁰⁹ The FDA had moved as early as 1997 to ban Ephedrine Alkaloids under dietary supplement safety provisions by issuing proposed rules,³¹⁰ but the FDA faced several difficulties, not the least of which was that under the DSHEA, the FDA had the burden of proof in banning Ephedrine Alkaloids.³¹¹

Finally, the FDA has recently taken action regarding weight loss dietary supplements. On April 1, 2004, the FDA announced that it had recently sent warning letters to sixteen weight loss dietary supplement manufacturers.³¹² Such warning letters stated that insufficient substantiation under the FDA notification and substantiation regulations for dietary supplement structure/function claims.³¹³

³⁰⁷62 Fed. Reg. 2217 (Jan. 15, 1997).

³⁰⁸69 Fed. Reg. 6787, 6788 (Feb. 11, 2004).

³⁰⁹Pub. L. No. 103-417, § 4 (codified at 21 U. S. C. § 342(f)). The final rule specifically utilizes the “unreasonable risk” standard for dietary supplements in 21 U. S. C. § 342(f)(1)(A). The final rule does not utilize the “significant risk” standard under 21 U. S. C. § 342(f)(1)(A), the “imminent hazard to public health or safety” standard under 21 U. S. C. § 342(f)(1)(C), or the adulteration standard for conventional foods under 21 U. S. C. § 342(a)(1) as applied to dietary supplements under 21 U. S. C. § 342(f)(1)(D). Further, because Ephedrine Alkaloids were not considered new dietary ingredients, the new dietary ingredient safety provisions under 21 U. S. C. § 342(f)(1)(B) and 21 U. S. C. § 350b were not applicable.

³¹⁰62 Fed. Reg. 30,677 (June 4, 1997).

³¹¹The FDA withdrew part of its proposed rule in 2000 due to receipt of new adverse event reports regarding Ephedrine Alkaloids and then twice reopened the comment period before issuing the final rule in 2004. 65 Fed. Reg. 17,474 (April 3, 2000); 65 Fed. Reg. 46,721 (July 31, 2000); 68 Fed. Reg. 10,417 (March 5, 2003).

³¹²Press Release, Food and Drug Administration, FDA Warns Distributors of Dietary Supplements Promoted Online for Weight Loss (April 1, 2004), available at <http://www.fda.gov/bbs/topics/news/2004/NEW01045.html> [hereinafter Weight Loss Press Release].

³¹³*See id.* For the notification and substantiation regulations, see discussion *supra*, Parts III.B.4, III.C.4. These warnings are especially important because there is mounting evidence that weight loss dietary supplements are not actually safe and effective. See Salynn Boyles, *Do Weight Loss Supplements Work?*, WEBMDHEALTH (April 2, 2004), available at <http://my.webmd.com/content/article/85/98401.htm> (last visited April 26, 2004). For more on the FDA’s regulation of weight loss dietary supplements and the improvements needed, see *When Diets Turn Deadly: Consumer Safety and Weight Loss Sup-*

8. Dietary Supplement Safety

While the DSHEA did enact new safety standards for dietary supplements,³¹⁴ the FDA has not passed general regulations concerning such safety standards.³¹⁵ Generally, the FDA must gather data on its own or through voluntary adverse event reporting from industry and then issue warning letters to manufacturers. The FDA has issued many such letters as well as taken other actions since passage of the DSHEA.³¹⁶ When the FDA feels it has gathered enough evidence to deem a dietary supplement unsafe, it can remove the substance from the market as it did with Ephedrine Alkaloids. The FDA's handling of Ephedrine Alkaloids seems to indicate that it is content to rely on the statutory language of the DSHEA for guidance and passive post-marketing surveillance systems.³¹⁷ However, in 1997 the FDA did issue one regulation concerning dietary supplement safety.³¹⁸ This regulation preserved the definition of "imminent hazard," which is one method by which a dietary supplement can be deemed adulterated under the DSHEA.³¹⁹ More recently, the FDA reaffirmed its commitment to dietary supplement safety.³²⁰

plements, Hearing Before Senate Subcomm. on Oversight of Gov't Mgmt., Restructuring and the Dist. of Columbia, Comm. on Gov't Affairs, 107th Cong. (2002) [Hereinafter House Weight Loss Hearing].

³¹⁴Pub. L. No. 103-417, § 4 (codified at 21 U. S. C. § 342(f)).

³¹⁵Instead the FDA has passed specific regulations that impact on dietary supplement safety (such as with GMPs, Ephedra, and new dietary ingredients).

³¹⁶See OFFICE OF THE INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ADVERSE EVENT REPORT FOR DIETARY SUPPLEMENTS – AN INADEQUATE SAFETY VALVE Appendix B (April 2001) [hereinafter OIG ADVERSE EVENT REPORT]. Recently, the FDA has taken such action with certain weight loss dietary supplements and androstendione. Weight Loss Press Release, *supra* note 312; Press Release, Department of Health and Human Services, HHS Launches Crackdown on Products Containing Andro (March 11, 2004), *available at* http://www.fda.gov/bbs/topics/news/2004/hhs_031104.html.

³¹⁷See discussion *supra*, Part. III.C.7, particularity note 309. As to passive post-marketing surveillance systems, see discussion *infra* Part III.E.1. In 1999, the CDSL endorsed such an approach to dietary supplement safety. CDSL Report, *supra* note 73, at vi.

³¹⁸62 Fed. Reg. 39,439 (July 23, 1997).

³¹⁹*Id.*; see 21 C. F. R. § 2.5. The DSHEA references this term in section 4 (codified at 21 U. S. C. § 342(f)(1)(C)). Dietary supplement safety may also be subject to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (June 12, 2002). The FDA issued interim final rules under this Act in 2003. See 68 Fed. Reg. 58,893 (Oct. 10, 2003).

³²⁰Press Release, Food and Drug Administration, Acting FDA Commissioner Dr. Lester M. Crawford Outlines Science-Based Plan for Dietary Supplement Enforcement (April 19, 2004), *available at* <http://www.fda.gov/bbs/topics/news/2004/NEW01055.html>.

D. Congressional Activity Regarding Dietary Supplements Post-DSHEA

While Part III.C above detailed the FDA's response to the DSHEA, this section provides a cursory view of congressional activity regarding dietary supplements post-DSHEA. Aside from the FDAMA, which is dealt with separately above, little legislation affecting dietary supplements has been enacted since the DSHEA.³²¹ One applicable piece of legislation is the Farm Security and Rural Investment Act of 2002.³²² This act deemed a dietary supplement to be misbranded [i]f it purports to be or is represented as ginseng, unless it is an herb or herbal ingredient derived from a plant classified within the genus *Panax*.³²³ The FDA subsequently proposed to incorporate this statutory restriction into regulations.³²⁴

1. Past and Pending Proposed Bills Concerning Dietary Supplements

In 1995, shortly after the DSHEA, a bill entitled The Food and Dietary Supplement Consumer Information Act of 1995 was introduced in the U.S. House of Representatives.³²⁵ The bill would have removed dietary supplements from the definition of food while also prohibiting them from being deemed drugs, thus creating a truly independent category of substances.³²⁶ The bill would also have repealed provisions of the DSHEA concerning nutrition content claims and health claims instead holding such claims to a new uniform stan-

³²¹The FDAMA and how it affected dietary supplements is discussed *supra*, Parts III.C.3, III.C.5.ii. Also the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and its effects on dietary supplements is discussed *supra* Part III.C.8, at note 319.

³²²Pub. L. No. 170-171, § 10806, 116 Stat. 143 (2002).

³²³*Id.* at § 10806(b)(2). The Act also stated that "the term 'ginseng' may only be considered to be a common or usual name (or part thereof) for any herb or herbal ingredient derived from a plant classified within the genus *Panax*; and... only labeling or advertising for herbs or herbal ingredients classified within that genus may include the term 'ginseng'." *Id.* at § 10086(b)(1).

³²⁴68 Fed. Reg. 51,738 (Aug. 28, 2003).

³²⁵H.R. 1951, 104th Cong. (1995).

³²⁶*Id.*

dard.³²⁷ No action was taken on this bill.

In subsequent years from 1995 through the present, numerous bills have been introduced in Congress pertaining to dietary supplements, but none have become law.³²⁸ There are also a number of bills concerning dietary supplements pending in the current Congress.³²⁹

2. Congressional Hearings Concerning Dietary Supplements

Since the DSHEA, there have also been a number of congressional hearings examining a variety of aspects of dietary supplements. The number of hearings are too numerous to list here,³³⁰ but a most recent hearing

³²⁷*Id.* CDSL Report, *supra* note 73, at 13. The proposed standard was that label claims must be truthful and not misleading. H.R. 1951, 104th Cong. (1995).

³²⁸*See, e.g.*, the Nutraceutical Research and Education Act, H.R. 3001, 106th Cong. (1999) (to establish a new legal classification and regulatory scheme for dietary supplements and foods with health benefits); the Consumer Health Free Speech Act, H.R. 1077, 106th Cong. (1999) (specifically excluding dietary supplements from the definition of drugs for purposes of making structure function claims and also increasing the burden of proof on the FDA to demonstrate a dietary supplement is adulterated); the Dietary Supplement Fairness in Labeling and Advertising Act, H.R. 3305 (1999), 106th Cong. (1999) (loosening both the restrictions on the regulation of scientific studies as labeling when used in conjunction with dietary supplements and the restrictions on dietary supplement advertising); the Consumer Freedom Protection Act, H.R. 4604, 106th Cong. (2000) (to allow for qualified health claims for dietary supplements consistent with *Pearson v. Shalala*); the Dietary Supplement Information Act, H.R. 3065, 107th Cong. (2001) (to require dietary supplement manufacturers to register with the FDA and supply the FDA with adverse event reports); the Health Information Independence Act of 2001, H.R. 3811, 107th Cong. (2002) (to establish a health claim review system for food and dietary supplement independent of the FDA).

³²⁹*See, e.g.*, the Dietary Supplement Information Act, H.R. 724, 108th Cong. (2003) (reintroduction of H.R. 3065, *supra* note 328); the Dietary Supplement Access and Awareness Act, H.R. 3377, 108th Cong. (2003) (to require manufacturers of dietary supplement to submit adverse event reports to the FDA and allowing for the Secretary to ban sales of dietary supplements to minors); the Health Information Independence Act, H.R. 4004, 108th Cong. (2004) (reintroduction of H.R. 3811, *supra* note 328); the DSHEA Full Implementation and Enforcement Act of 2003, S. 1538, 108th Cong. (2003) (to authorize appropriations and institute accountability to ensure that the goals of the DSHEA are met); the Dietary Supplement Tax Fairness Act of 2003, H.R. 2627, 108th Cong. (2003) (to treat amounts paid for dietary supplements as medical expenses for tax purposes). Additionally, prior to the FDA's issuance of its final rule on Ephedrine Alkaloids, numerous bills on this subject were introduced in the 108th Congress. *See, e.g.*, the Ephedrine Alkaloids Consumer Protection Act, H.R. 275, 108th Cong. (2003).

³³⁰*See, e.g.*, *Dietary Supplement Health and Education Act: Is the FDA Trying to Change the Intent of Congress?*, Hearing Before the House Comm. on Gov't Reform, 106th Cong. (1999); *Six Years After of DSHEA: The Status of National and International Dietary Supplement Research and Regulation*, Hearing Before the House Comm. on Gov't Reform, 107th Cong. (2001); *Hearing on Diet, Physical Activity and Dietary Supplements Before the House Comm. on Gov't Reform*, 107th Cong. (2002); House Weight Loss Hearing, *supra* note 313; *Hearing on Dietary Supplements Containing Ephedra Before Senate Subcomm. on Oversight of Gov't Mgmt., Restructuring and the Dist. of Columbia*, Comm. on Gov't Affairs, 107th Cong. (2002); *Joint Hearing on Issues Relating to Ephedra Dietary Supplements Before House Subcomm. on Commerce, Trade, and Consumer Prot., Comm. on Energy and Commerce*, 108th Cong. (2003).

in 2004 is instructive.³³¹ This hearing was held on the 10th anniversary year of the DSHEA to ensure “federal health agencies and the dietary supplement industry have maintained the integrity of this act, so that Congress might consider ways in which the act could be improved and educate American consumers to the latest developments in dietary supplement policy and nutritional labeling practices.”³³² One U.S. House Rep. noted that regarding dietary supplement safety, the DSHEA forces the FDA to act after the fact when substantial harm may have already occurred.³³³ In that regard, another congressman noted that he would like to see mandatory adverse event reporting for dietary supplement manufacturers.³³⁴ However, the director of the FDA Center for Food Safety and Applied Nutrition (“CFSAN”) testified that the FDA is not seeking additional legislation for dietary supplements because it believes the DSHEA provides an adequate framework.³³⁵

E. Additional Post-DSHEA Industry Activity Regarding Dietary Supplements

This section presents a fraction of the notable industry activity that has taken place regarding dietary supplements post-DSHEA.

1. Dietary Supplement Safety and Adverse Event Reporting

Post-DSHEA, there has been considerable industry involvement regarding the safety of dietary supplements.

First, after passage of the DSHEA, the FDA was faced with a sizable challenge regarding dietary supplement

³³¹ *Hearing on Dietary Supplements Before the House Subcomm. on Human Rights and Wellness, Comm. on Gov’t Reform*, 108th Cong. (2004) [hereinafter 2004 House Hearing].

³³² *Id.* at 3 (statement of Rep. Dan Burton, Chairman, House Comm. on Gov’t Reform).

³³³ *Id.* at 6 (statement of Rep. Susan Davis).

³³⁴ *Id.* at 10 (statement of Sen. Richard Durbin). One industry group supported this. *Id.* at 41 (statement of Annette Dickinson, President, Council for Responsible Nutrition).

³³⁵ *Id.* at 15-16 (statement of Dr. Robert Brackett, Director, FDA Center for Food Safety and Applied Nutrition). Dr. Brackett did concede that the voluntary adverse reporting system was not particularly robust, but he did point out that a new adverse event reporting system is now in place for dietary supplements. *See id.* at 18, 20.

safety. Specifically, it was not enabled by the DSHEA to institute a premarket review system for dietary supplements marked for use in the United States prior to October 15, 1994.³³⁶ To decide then how to ensure the safety of such dietary supplements, the FDA turned to the National Academies, including the Institute of Medicine (“IOM”), to develop a framework for evaluating dietary supplement safety. In 2002 the IOM issued a proposed framework,³³⁷ and just recently the IOM released its final report.³³⁸ The report contains a detailed framework for the FDA to follow in order to ensure the safety of dietary supplements³³⁹

As mentioned in Part III.C.8, the FDA must rely on post-market surveillance and voluntary adverse event reporting to review the safety of dietary supplements (at least for those dietary supplements not falling within the new dietary ingredient provision of the DSHEA). Two major reports have addressed the effectiveness of such a system for dietary supplement safety. First, in 2000 the General Accounting Office (“GAO”) issued a report on the safety of dietary supplements and functional foods.³⁴⁰ The report concludes that there is limited assurance of safety for dietary supplement and functional foods.³⁴¹ The report attributed this to the absence of guidance and regulations for dietary supplements in many areas including removal of unsafe

³³⁶See Pub. L. No. 103-417, § 4 (codified at 21 U. S. C. § 342(f)), § 8 (codified at 21 U. S. C. § 350b).

³³⁷INSTITUTE OF MEDICINE, PROPOSED FRAMEWORK FOR EVALUATING THE SAFETY OF DIETARY SUPPLEMENTS (2002).

³³⁸INSTITUTE OF MEDICINE, DIETARY SUPPLEMENTS: A FRAMEWORK FOR EVALUATING THE SAFETY OF (2004) [hereinafter IOM Report].

³³⁹*Id.* In short, the FDA can either proactively initiate a review of a dietary supplement or can wait to receive a signal indicating the possibility of serious health problem regarding the dietary supplement. *Id.* at 3-3 to 3-4. The FDA would then make an initial review of the available information and determine the level of concern it has about the dietary supplement. *Id.* at 3-5. If the level of concern is low, the FDA could monitor and continue to collect data. *Id.* If the level of concern is high the FDA could take immediate action. *Id.* If the level of concern is moderate or it is high but the FDA does not want to take immediate action, the FDA would engage in an integrative evaluation. *Id.* at 3-5 to 3-6. The integrative evaluation contains four parts: “in-depth literature search and review, drafting of a safety monograph based on this information, integrating the available data into an analysis to complete the monograph, and possibly referring the draft monograph to an expert committee for additional input.” *Id.* at 3-6. The FDA is to enter at step three, examine the draft monograph, and then take regulatory action, take no action and continue to monitor, or proceed with step four by referring the monograph to an expert committee for review. *Id.* at 3-9 to 3-10. If the FDA proceeds with step four, the expert committee is to submit a report to FDA after which the FDA will decide whether to take action or to continue to monitor. *Id.* at 3-11. As part of its report, the IOM prepared six prototype monographs for the dietary supplements chaparral, chromium picolinate, glucosamine, melatonin, saw palmetto, and shark cartilage. *Id.* at appendices D to I. The full monographs are available at <http://www.iom.edu/subpage.asp?id=19554> (last visited April 22, 2004).

³⁴⁰UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY – IMPROVEMENTS NEEDED IN OVERSEEING THE SAFETY OF DIETARY SUPPLEMENT AND FUNCTIONAL FOODS (July 2000) [hereinafter GAO Safety Report].

³⁴¹*Id.* at 12.

products and the making of structure/function claims as well as a lack of a clearly defined boundary between dietary supplements and functional foods in conventional form.³⁴²

A second major safety report was issued in 2001 by the Office of the Inspector General of the Department of Health and Human Services. It concerned the FDA's adverse event reporting system for dietary supplements.³⁴³ "An adverse event is an incident of illness or injury that *may* be associated with a product or ingredient."³⁴⁴ The FDA must rely on consumers, health professionals, and dietary supplement manufacturers for these reports as such reporting is entirely voluntary.³⁴⁵ The 2001 report concludes that the FDA's adverse event reporting detected only a small amount of such events for dietary supplements and as a result the FDA rarely took responsive safety actions.³⁴⁶ Such problems were attributed to the limited information the FDA receives and the lack of a well developed system for analyzing such information.³⁴⁷ The FDA responded to this report in announcing the creation of the CFSAN Adverse Event Reporting System ("CAERS")³⁴⁸. CAERS is eventually to form a centralized reporting system for all CFSAN regulated products (including all dietary supplements) by replacing previous decentralized and uncoordinated FDA adverse event reporting systems.³⁴⁹ As of 2004, the effectiveness of CARES has yet to be proven.³⁵⁰

³⁴²*Id.* at 13-25. Specifically, the report found that the FDA lacked guidance regarding the use and safety of new dietary ingredients and also lacked consistent standards on the removal of unsafe dietary supplements. *Id.* at 15. Further, the report found a lack of FDA guidance on requiring safety information on dietary supplement labels, lack of an effective FDA system for adverse event reporting, and lack of consistent FDA guidance on the making of structure/function claims on dietary supplement labels. *Id.* at 15-21. Finally, the report found that the difference between structure/function claims and health claims was not understood by consumers leading to consumer confusion over what such claims meant. *Id.* at 23-25. The report also made formal recommendations to the FDA for correcting these deficiencies. *Id.* at 27. For the FDA's response to a draft of this report, *see id.* at appendix II.

³⁴³OIG ADVERSE EVENT REPORT, *supra* note 316.

³⁴⁴*Id.* at i.

³⁴⁵*Id.* at i, 4.

³⁴⁶*Id.* at ii-iii, 9-18.

³⁴⁷*Id.* at 9-18.

³⁴⁸CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, ANNOUNCING CAERS – THE ADVERSE EVENT REPORTING SYSTEM (Aug. 29, 2002), *available at* <http://www.cfsan.fda.gov/~dms/caersltr.html>.

³⁴⁹*Id.*

³⁵⁰*See* 2004 House Hearing, *supra* note 331, at 20 (statement of statement of Dr. Robert Brackett, Director, FDA Center for Food Safety and Applied Nutrition).

Finally, there are also industry based safety measures in place. The National Nutrition Foods Association (“NNFA”) conducts the TruLabel program which all of its members (manufacturing dietary supplements under their own label) must join.³⁵¹ This program ensures that the dietary supplement labels of all participants comply with all FDA regulations.³⁵²

2. Dietary Supplement Analysis

A further area of industry action regarding dietary supplements concerns dietary supplement analysis performed by the Association of Analytical Communities International (“AOAC”). The AOAC is under contract with the FDA and the National Institutes of Health to develop “reliable analytical methods... to verify ingredient identity and measure the amounts of declared ingredients” in dietary supplements.³⁵³ Such action will certainly aid the FDA in ensuring dietary supplement safety.

F. Dietary Supplement Advertising Regulation

As with any consumer product, advertising plays an important role for dietary supplements. Not only do retail outlets engage in advertising for dietary supplements, but so too do dietary supplement manufacturers through the use of medical journals, television, radio, magazines, retail trade publications, and public relations campaigns.³⁵⁴

³⁵¹NATIONAL NUTRITIONAL FOODS ASSOCIATION, NNFA TRULABEL PROGRAM, *available at* http://www.nnfa.org/services/science/bg_Trulabel.htm#over (last visited April 22, 2004) [hereinafter TRULABEL]. For empirical information about dietary supplement labeling and claims (at least as of 1999) *see* DIETARY SUPPLEMENT SALES INFORMATION, *supra* note 44, at 5-5 to 5-11.

³⁵²TRULABEL, *supra* note 351. The NNFA also conducts a GMPs program for dietary supplement manufacturer members. *See* NATIONAL NUTRITIONAL FOODS ASSOCIATION, NNFA GMP CERTIFICATION PROGRAM OVERVIEW, *available at* <http://www.nnfa.org/services/science/gmp.htm> (last visited April 22, 2004).

³⁵³James Giese, *Dietary Supplement Analysis*, FOOD TECHNOLOGY, Aug. 2003, at 92; AOAC International, Call for Methods for Saw Palmetto, SAME, Vitamin E, CoEnzyme Q₁₀, *Panaxquinquefolius*, *Panax ginseng*, Eleuthero, Kava Kava, Yohimbe and Cranberry, *available at* http://www.aoac.org/dietsupp/Call_11_05_2003.pdf (last visited April 23, 2004).

³⁵⁴ECONOMIC CHARACTERIZATION, *supra* note 4, at 5-13.

The Federal Trade Commission (“FTC”) is responsible for regulating advertising claims for all foods, including dietary supplements. Specifically, the FTC may prohibit the dissemination of false or misleading dietary supplement advertising.³⁵⁵ The FTC requires that dietary supplement advertising be truthful and not misleading and have adequate substantiation for all claims.³⁵⁶ The FTC tries to harmonize its enforcement of advertising claims with the FDA’s enforcement of claims in food and dietary supplement labels.³⁵⁷ However, there are situations where these enforcement approaches do not meet up.³⁵⁸

Several bills were introduced in Congress in the late 1990s to remedy different standards of enforcement between the FDA and FTC. In 1998 the Dietary Supplement Fairness in Advertising Act was introduced in the U.S. House of Representatives.³⁵⁹ The bill would have ensured that dietary supplement advertising that met the provisions of the FDCA and DSHEA and made certain disclosures about studies used in making advertisement claims would not constitute unfair competition or deceptive trade practices under the FTC statutory provisions.³⁶⁰ In 1999, the Dietary Supplement Fairness in Labeling and Advertising Act was introduced in Congress to exempt all dietary supplement publications considered labeling under the DSHEA (specifically 21 U. S. C. § 342-2) from regulation as advertising by the FTC.³⁶¹ Neither of these bills became law and no bills on this topic are currently pending in Congress.

³⁵⁵15 U. S. C. §§ 52, 55. Section 52 states that the dissemination of any false advertisement constitutes “an unfair or deceptive practice” under 15 U. S. C. § 45 (granting general authority to the FTC to regulate unfair or deceptive practices).

³⁵⁶FEDERAL TRADE COMMISSION, FTC POLICY STATEMENT ON DECEPTION (Oct. 14, 1983), available at <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>; FEDERAL TRADE COMMISSION, FTC POLICY STATEMENT REGARDING ADVERTISING SUBSTANTIATION (1983), available at <http://www.ftc.gov/bcp/guides/ad3subst.htm>; FEDERAL TRADE COMMISSION, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY 3, available at <http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm> [hereinafter ADVERTISING GUIDE]. Specifically, the FTC will look to all express and implied claims made by the advertising, the types of disclosure made in the advertising, and whether the advertiser has a reasonable basis for all express and implied claims. ADVERTISING GUIDE, *supra*, at 3-18.

³⁵⁷See 59 Fed. Reg. 28,388 (June 1, 1994) (the FTC’s Enforcement Policy Statement on Food Advertising); GAO Safety Report, *supra* note 340, at 22; ADVERTISING GUIDE, *supra* note 356, at 24-25 (the FTC will generally follow the FDA’s labeling approach under the DSHEA for third party advertising).

³⁵⁸For example, in some situations the FTC may allow a qualified health claim to be made in dietary supplement advertising while the FDA would not allow such a claim on the dietary supplement label. GAO Safety Report, *supra* note 340, at 22. As another example, use of the label disclaimer required under the DSHEA for statements of nutritional support in dietary supplements may not constitute adequate disclosure under FTC advertising regulations. ADVERTISING GUIDE, *supra* note 356, at 23.

³⁵⁹H.R. 4581, 105th Cong. (1998).

³⁶⁰*Id.*

³⁶¹H.R. 3305, 106th Cong. (1999). The same bill was introduced in the Senate. See S. 1749, 106th Cong. (1999).

IV. RECOMMENDATIONS REGARDING FUTURE REGULATION OF DIETARY SUPPLEMENTS

This section discusses some recommendations for both the FDA and Congress concerning dietary supplement regulation.

It could not be expected that the massive changes the DSHEA enacted for dietary supplement could be swiftly and seamlessly detailed and implemented by the FDA. Ten years later, the FDA has made a serious effort to implement most all of the provisions of the DSHEA with varying amount of success and failure. However, the FDA still has plenty of work to do regarding dietary supplements.

One area that needs further improvement is general dietary supplement safety. By excluding most dietary supplements from drug regulations and excluding all dietary supplements from regulation as food additives, the DSHEA greatly freed up manufacturers of dietary supplements. Dietary supplements are not subject to premarket approval like drugs, nor must they be shown to be GRAS or otherwise comply with the Food Additives Amendment of 1958 like all conventional food. However, this places an enormous safety burden on the FDA, a burden which all too often the FDA has failed to carry.³⁶² The FDA's action regarding Ephedrine Alkaloids demonstrated the costs of having to meet such heavy burdens.³⁶³ There are several ways to remedy this. First, the FDA's creation of CARES, a unified adverse event reporting system, is a step in the right direction. Second, adverse event reporting should be made mandatory. All dietary supplement

³⁶²Some of this slack is picked up by the NNFA's TruLabel program. *See* discussion *supra* Part III.E.1. This program should certainly continue and expand in scope to reach industry wide.

³⁶³*See* discussion *supra* Part III.C.7.

manufacturers should be required to submit adverse event reports to the FDA as they become available to such manufacturers. Third, all manufacturers of dietary supplements should be required to register with the FDA.³⁶⁴ This would greatly strengthen the FDA's ability to detect signals relating to dietary supplement safety. Fourth, the FDA should also adopt the detailed framework for dietary supplement safety recently submitted to the FDA by the IOM, which would create a detailed FDA post-market surveillance system for dietary supplements.³⁶⁵ Finally, while the FDA has implemented notification procedures for new dietary ingredients, it has not implemented guidance on the amount and type of evidence needed in this notification to demonstrate the safety of new dietary ingredients.³⁶⁶ Such guidance is greatly needed in order to provide the dietary supplement industry with standards by which to test and produce new dietary supplements. And additional area that needs improvement is the making of claims of nutritional support on dietary supplement labels. Claims of nutritional support, and particularly structure/function claims and health claims (both qualified and unqualified) are currently subject to varied and numerous regulations. However, there is still consumer confusion and inability to distinguish between such claims.³⁶⁷ One possible solution might be to create an agency independent of the FDA to handle and review statements of nutritional support for dietary supplements in a consistent manner while clearly defining the differences in each type of claim.³⁶⁸ Harmonizing FDA and FTC regulations in this area would also be helpful and would lessen consumer confusion.³⁶⁹

³⁶⁴A bill currently pending in the House would require this as well as mandatory adverse event reporting. See Dietary Supplement Information Act, H.R. 724, 108th Cong. (2003). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and its registration requirements for food manufacturers are steps in this direction. See discussion *supra* notes 319, 321.

³⁶⁵See IOM Report, *supra* note 338.

³⁶⁶The FDA was alerted to this need in 2000. See GAO Safety Report, *supra* note 340, at 27.

³⁶⁷See GAO Safety Report, *supra* note 340, at 23-25.

³⁶⁸A bill currently pending in the House would require this type of independent review system for health claims in dietary supplements and other nutritional foods. See Health Information Independence Act, H.R. 4004, 108th Cong. (2004). A less drastic but still satisfying solution would be the FDA's ANPRM proposal of subjecting all qualified health claims to a new post-market review system. See 68 Fed. Reg. 66,040 (Nov. 25, 2003); see also discussion *supra* Part III.C.5.iii.

³⁶⁹See discussion *supra* Part III.F for several bills that proposed a version of this.

Finally, the FDA should work to better distinguish dietary supplements from conventional foods. As nutrition has become more important to society, the line between dietary supplements and functional yet conventional foods has blurred. And while the DSHEA does require a dietary supplement to be labeled as such, its allowance for dietary supplements to be marketed in conventional food form in certain circumstances only adds to the confusion. The FDA should seek to explain these boundaries both for manufacturers and for consumers through new regulations and public relations campaigns.³⁷⁰ Because of the similarity between functional foods and dietary supplements, perhaps a new category of regulation should be created combining these two product types.³⁷¹ This new category could take these more “drug like” products for which structure/function and various health claims are made and subject them to uniform claim procedures separate from conventional foods.

V. CONCLUSION

Dietary supplements are interstitial – spaced between conventional foods and drugs. However, this status has not affected their popularity, which has been and continues to be unprecedented. While Congress and the FDA wrestled for decades with how to treat dietary supplements, they took a strong stance with the DSHEA and subsequent regulations. The DSHEA considered dietary supplements to be food but also subjected dietary supplements to some standards applied neither to food nor drugs. This categorization has fit, but imperfectly. The history of dietary supplement regulation since the DSHEA is one of trying to force a previously undefined product group into unsuitable clothing and of trying to ensure availability of a popular product group while also ensuring safety. Real progress has been made, but the unsettling question still

³⁷⁰The FDA was alerted to this need in 2000. See GAO Safety Report, *supra* note 340, at 27.

³⁷¹In 1999, a bill proposing a version of this was introduced in the House. See Nutraceutical Research and Education Act, H.R. 3001, 106th Cong. (1999).

remains: where is the line between a food and a drug? The DSHEA has given the FDA the tools to search for the line, but in this era of emphasis on nutrition and functional foods additional, or at least refurbished, tools may be required.